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November 28, 2001

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Attn: 8(d) Health and Safety Data Reporting Rule (Notification/Reporting)

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Re: For Your Information Submission:  
58 FR 28511 (May 14, 1993) [OPPTS-82040; FRL-4271-1]  
TSCA Section 8(d) Health and Safety Data Reporting

Dear Sir:

The enclosed information is submitted on behalf of Dow Corning Corporation, Midland, Michigan, 48686-0994, on a For-Your-Information (FYI) basis as a follow-up to submissions made concerning di-Me siloxanes and silicones (polydimethylsiloxane, PDMS), which chemical substance was the subject of a health and safety data rule issued under Section 8(d) of the Toxic Substances Control Act (TSCA) and with an effective date of June 14, 1993 (sunset date June 30, 1998), as codified at 40 CFR 716 (Health and Safety Data Reporting). The information presented in this submission was generated as part of our Siloxane Research Program. This program was the subject of a memorandum of understanding, dated April 9, 1996, between Dow Corning and EPA.

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**Chemical Substance:**

63148-62-9 Siloxanes and Silicones, di-Me (PDMS)

**Title of Report:**

DISPOSITION OF POLYDIMETHYLSILOXANE, 350 CST IN FISCHER 344  
RATS FOLLOWING A SINGLE EXPOSURE BY ORAL GAVAGE

Dow Corning Corporation  
2001-I0000-50844  
November 21, 2001



FYI-01-001416

Contain NO CBI



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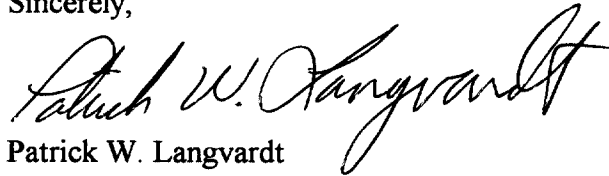
**Manufacturer:**

Dow Corning Corporation  
2200 West Salzburg Road  
Midland, Michigan 48686-0994

For purposes of this For-Your-Information (FYI) submission, the general INTERNAL designation on the attached health and safety report is waived by Dow Corning.

If you require further information regarding this submission, please contact Dr. Rhys G. Daniels, Senior Regulatory Compliance Specialist, Product Safety and Regulatory Compliance, at 989-496-4222 or at the address provided herein.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick W. Langvardt". The signature is fluid and cursive, with the first name "Patrick" being more prominent.

Patrick W. Langvardt  
Director of Health and Environmental Sciences  
989-496-4626

RGD01372

**DOW CORNING CORPORATION  
HEALTH & ENVIRONMENTAL SCIENCES  
TECHNICAL REPORT**

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Report No.: 2001-I0000-50844

Title: Disposition of Polydimethylsiloxane, 350 cst in Fischer 344  
Rats Following a Single Exposure by Oral Gavage

Study No.: 9345

Test Article:  $^{14}\text{C}$ -Polydimethylsiloxane, 350 cst ( $^{14}\text{C}$ -PDMS, 350 cst)

Study Director: Marina L. Jovanovic, M.S.  
Associate Toxicology Specialist

Sponsor: Dow Corning Corporation

HES Management: Kathleen P. Plotzke, Ph.D.  
Manager, Toxicology  
Health and Environmental Sciences

Testing Facility: Dow Corning Corporation  
Health and Environmental Sciences  
Midland, MI 48686

Study Completion Date: November 21, 2001

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## ABSTRACT

The absorption of neat  $^{14}\text{C}$ -polydimethylsiloxane, 350 cst ( $^{14}\text{C}$ -PDMS) from the gastrointestinal (GI) tract was evaluated in female and male Fischer 344 rats following a single oral exposure to 1000 mg per kg of body weight. The study consisted of two main parts defined by the methodology that was used to follow distribution of test article after administration via oral gavage. The first part of the study (Mass Balance part) consisted of 2 exposure groups (one group of 4 females and one group of 4 males) that were housed in the Roth-style glass metabolism cages for 96 hr after exposure for the collection of excreta. Housing animals in the metabolism cages after administration of the test article enabled assessment of the total radioactivity recovery (mass balance). Also, additional experiments were conducted to substantiate PDMS content that was excreted in feces by achieving better extraction efficiencies. Excreta and tissues collected in the control groups (animals not dosed) were used to evaluate matrix background effects. In the second part of the study, whole-body autoradiography (WBA) was utilized for the *in vivo* assessment of tissue distribution of radiolabeled PDMS at 12, 24, 48 and 96 hr post-dose.

Virtually all  $^{14}\text{C}$ -PDMS, 350 cst fluid was rapidly excreted following oral administration. Both quantitative assessment by liquid scintillation analysis of the mass balance group, and qualitative assessment by WBA showed that radioactivity was rapidly excreted through the gastrointestinal tract. The total dose recovery ( $\pm$  standard error of the mean) in female rats was  $93.61 \pm 0.72\%$  and in male rats  $97.42 \pm 0.58\%$ , when corrected for solubilization processing efficiency (92%). Resulting radioactivity excretion and overall dose recovery was significantly greater in males than in females (97.42% vs. 93.61%). Nearly all recovered dose was excreted in feces representing 99.98% of the total recovered dose in both female and male rats. In addition, WBA data at 12, 24 and 48 hours post-dosing showed that radioactivity was concentrated in the contents of the GI tract. No radioactivity was detected in organs or tissues outside the GI tract with the possible exception of exterior contamination at the earlier time points (12 and 24hr post dose). Total elimination of administered PDMS was observed on autoradiographs 96 hours after dosing. Also, only 0.004% and 0.001% of administered dose was detected by liquid scintillation analysis in harvested tissues and remaining carcasses of females and males, respectively 96 hour post-dose. There were no statistically significant differences in PDMS absorption or distribution between male and female rats.

Feces analyses showed that all of the radioactivity recovered in feces by extraction could be attributed to the unchanged PDMS, 350 cst. The results of HPLC analyses of the 12-, 24- and 48- hour fecal samples gave similar radioactivity profiles as a solvent standard of PDMS, 350 cst as well as matrix standards spiked with PDMS, 350 cst (extracts of spiked control fecal homogenates) indicating that no detectable metabolites or degradation products were present in feces following single administration of PDMS, 350 cst. Overall, data indicate that PDMS, 350 cst was rapidly excreted in feces unchanged following oral administration.



## GLP COMPLIANCE STATEMENT

The study was conducted in compliance with Environmental Protection Agency Toxic Substance Control Act Good Laboratory Practice Regulations 40 CFR part 792, except for the use of software SAS<sup>®</sup>, v. 8.0 that was not validated to the GLP standards. Deviations to the Protocol are listed in the Experimental Design section of this report. There were no circumstances that would negatively impact or bias the results of this study.

The Dow Corning Health and Environmental Sciences (HES) Quality Assurance Unit monitored the study in accordance with Dow Corning HES Standard Operating Procedures.

Marina Jovanovic

Marina L. Jovanovic, M.S.

Study Director

11-21-2001

Date

Kathleen P. Plotzke

Kathleen P. Plotzke

Manager, Toxicology

Health and Environmental Sciences

11-21-01

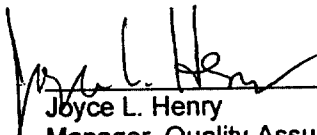
Date

Title: Disposition of Polydimethylsiloxane, 350 cst in Fischer 344 Rats Following a Single Exposure by Oral Gavage

Study Number: 9345

This study has been audited by the Dow Corning Corporation Health and Environmental Sciences Quality Assurance Unit according to approved Standard Operating Procedures to assure that the raw data are accurately reflected within this final report. The following are the inspection dates and the dates inspection findings were reported.

<u>Dates of Inspection</u>	<u>Phase Inspected</u>	<u>Findings Reported to Study Director</u>	<u>Findings Reported to Management</u>
15 Nov 99	Draft Protocol Review	15 Nov 99	15 Dec 99
16 Feb 00	Dose Solution Preparation	17 Feb 00	28 Feb 00
21 Feb 00	Terminal Sacrifice and Tissue/Blood Collection	28 Feb 00	29 Feb 00
28 Mar 00	Sample Prep (Fecal)	30 Mar 00	05 Apr 00
13 Nov 01	Wet Specimen Verification	14 Nov 01	19 Nov 01
8-15 Oct 01	Draft Final Report and Associated Raw Data Review	18 Oct 01	07 Nov 01

  
Joyce L. Henry  
Manager, Quality Assurance  
Dow Corning Corporation  
Health & Environmental Sciences

20 Nov 01  
Date

## APPROVAL SIGNATURES

This report consists of pages 1 through 157 including Tables 1 through 8, Figures 1-4 and Appendices A through D.

---

*Marina Jovanovic*

*11-21-2001*

Marina L. Jovanovic, M.S.

Date

Associate Toxicology Specialist

Study Director

---

*Kathleen P. Plotzke*

*11-21-01*

Kathleen P. Plotzke, Ph.D.

Date

Manager, Toxicology

Health and Environmental Sciences

**STUDY INFORMATION**

Study Initiation Date:	11/29/99
Experimental Start Date:	02/17/2000
Experimental Termination Date:	05/10/2001
Study Completion Date:	November 21, 2001
Study Director:	Marina L. Jovanovic, M.S. Associate Toxicology Specialist
Sponsor:	Dow Corning Corporation 2200 W. Salzburg Rd. Midland, MI 48686-0994
Management:	Kathleen P. Plotzke, Ph.D. Manager, Toxicology Health and Environmental Sciences
Key Study Personnel:	Earnestine Stanton, Study Coordinator Joseph M. Tobin, Supervisor Jeremy Durham
Consulting Veterinarian:	Lawrence P. Ruhr, D.V.M. , Ph.D Ruhr & Associates Midland, MI
Contributing scientist:	Debra A. McNett, B.S. Associate Bioanalytical Specialist  Jane M. Regan, HT/MLT (ASCP) Technologist
Statistician:	Robert H. Gallavan, Jr. Ph.D. Biostatistician Specialist

## OBJECTIVE

The objective of this study was to determine disposition of the test material  $^{14}\text{C}$ -polydimethylsiloxane, viscosity 350 cst ( $^{14}\text{C}$ -PDMS), from the gastrointestinal (GI) tract of Fischer 344 rats.

## INTRODUCTION

Linear polydimethylsiloxanes (PDMS) have a wide range of industrial and consumer uses, either in pure form or as an ingredient of formulated products. The viscosities of PDMS fluids mainly used are 350 and 1000 cst, although other viscosities are used for specialized purposes. The main routes of direct human exposure to PDMS are skin contact (personal care products) and oral intake (food application). Oral gavage is customary and an accepted method of administration of test chemicals in pharmacokinetics and metabolism studies.

Experimental design of this study follows test guidelines and Tier 1 data requirements for the health effects testing of pesticides and toxic substances issued in August 1998 by the United States Environmental Protection Agency (EPA) (3). Previous studies, such as "A 28-Day Oral Toxicity Study of Dow Corning 200® Fluid, 350 cst in Rats" (7), "90-Day Subchronic Oral Toxicity study with Polydimethylsiloxane Fluid in Male Rats" (6), "Single and repeated dose pharmacokinetic studies of polydimethylsiloxanes in the rat" (5), "A Method Development Study to Develop Techniques for Whole-Body Autoradiography Following Exposure to DC 200® Fluids" (4) showed that PDMS fluids are rapidly excreted from the GI tract of rats after oral administration by gavage or with the basal diet.

In this study, whole-body autoradiography (WBA) was utilized in addition to using classical techniques for determining absorption by using Roth-style glass metabolism cages for housing animals. WBA has been successfully used in previous studies for the *in vivo* assessment of tissue distribution of radiolabeled compounds and potential metabolites. WBA is also valuable for tracking the transient time of radioactivity through the gastrointestinal tract. Because of the physicochemical properties of PDMS, methods were developed (4) that allowed adaptation of this technique for qualitative assessment of PDMS in conjunction with the quantitative assessment of PDMS excretion and absorption using radiotracers.

## TEST ARTICLE INFORMATION

Test article characterization was done in compliance with the EPA Toxic Substances Control Act (TSCA), Good Laboratory Practice (GLP) Regulations (40CFR Part 792). Results of test article characterization were reviewed by the study director.

### A. Unlabeled Test Article

The characterization of the unlabeled test article (PDMS, 350 cst) identified below included a visual inspection, Fourier transform infrared spectroscopy (FTIR), viscosity, purity by gas chromatography (GC) with flame ionization detection (FID) (1). In addition, detection limit investigation by GC/FID indicated that PDMS, 350 cst has less than 0.03% each by weight D<sub>4</sub>, D<sub>5</sub> and D<sub>6</sub> (1). Records of characterization are maintained in the HES Archive.

Identification:	Polydimethylsiloxane, 350 cst (supplied as Dow Corning® 200 Fluid, 350 cst)
Lot Number:	LL068057
CAS Number:	63148-62-9
Physical Description:	Colorless liquid, refer to MDMS and MSDS
Chemical stability:	Stable, refer to MSDS
Expiration Date:	June 30, 2001
Purity:	The test article is representative of polydimethylsiloxane, 350 cst and is considered pure
Solubility:	Soluble in toluene, hexane, acetone, ethanol, tetrahydrofuran etc. (8,9)
Test article characterization:	HES Study No. 9294, TIS Report No. 2000-10000-48210
Storage Conditions:	Room temperature (refer to MDMS)
Supplier:	Dow Corning Corporation 2200 W. Salzburg Road Midland, MI 48686-0994
Reserve Sample:	A sample is retained in the HES Test Article Archives, Dow Corning Corporation Midland, MI 48686-0994

**B. Labeled Test Article**

Chemical identity and radiochemical purity of the labeled test article ( $^{14}\text{C}$ -PDMS), identified below, was done using FTIR and high performance liquid chromatography (HPLC) with a radioactivity flow-through detector, respectively (2,10). Detection limit investigation by GC/FID indicated that concentration of  $\text{D}_4$  in  $^{14}\text{C}$ -PDMS, 350 cst was slightly higher than 0.03% by weight, while the concentrations of  $\text{D}_5$  and  $\text{D}_6$  were less than 0.03% each by weight. The molecular weight distribution of  $^{14}\text{C}$ -PDMS, 350 cst from the gel permeation chromatography (GPC) analysis was consistent with molecular weight distribution of the reference article, PDMS 350 cst. Records of characterization are maintained in the HES Archive. Any remaining test article was returned to Test Article Control area.

Identification:	$^{14}\text{C}$ -Polydimethylsiloxane, 350 cst
Reference Number	10671-64
Specific Activity:	0.52 mCi/g
Radiochemical Purity:	100 %
Solubility:	Soluble in organic solvents, such as hexane, toluene, tetrahydrofuran, etc. (8,9)
Physical Description:	Colorless liquid (refer to MSDS)
Handling Precautions:	Good ventilation recommended, wear impervious gloves, safety glasses with side shields or safety goggles
Chemical stability:	Stable (refer to MSDS). Very stable in air and light, but can hydrolyze under strongly acid or basic conditions. Stable in organic solvents, according to the information provided by the sample submitter
Expiration Date:	May 16, 2003 (10)
Test article characterization:	HES Study No. 9271, TIS Report No. 1999-I0000-48279 and HES Study No. 9579. FTIR, GC/FID and GPC
Storage Conditions:	Refrigerator ( $4^\circ\text{C} \pm 4^\circ\text{C}$ ) or room temperature, according to the information provided by the sample submitter.

Supplier: Dow Corning Corporation  
Health and Environmental Sciences  
2200 W. Salzburg Road  
Midland, MI 48686-0994

Reserve Sample: A sample retained in the HES Test Article  
Archives, Dow Corning Corporation  
Midland, MI 48686-0994

## ROUTE OF EXPOSURE

Oral administration of the test article was selected as the exposure route since this represents a potential route for human exposure and is an accepted method of administration of test chemicals in pharmacokinetics and metabolism studies.

## TEST SYSTEM

A. Species: Rattus norvegicus

B. Strain: CDF® (Fischer 344)/CrIBR

C. Source: The Charles River Breeding Laboratories, Inc.  
Raleigh, NC

D. Sex: Female and Male

E. Number of groups: 8

F. Number of animals:

Part 1 (mass balance, MB):	Group 1 (controls):	2 females
	Group 2 (controls):	2 males
	Group 3:	4 females
	Group 4:	4 males
Part 2 (whole body autoradiography):	Group 5:	4 females and 4 males
	Group 6 (spares):	4 females and 4 males
Part 3 (additional dosing experiment):	Group 7 (controls):	1 female and 1 male
	Group 8:	2 females and 2 males

G. Total Number: 34 (17 females and 17 males)

## H. Special Consideration:

In Part 1 of the study, rats were randomized and assigned to the groups 1, 2, 3 and 4.

In Part 2 rats were not randomized.

In Part 3 rats were randomized and assigned to the groups 7 and 8.

## I. Body Weight Range:

Females: 145-161 g at experimental start

Males: 175-202 g at experimental start

## J. Approximate Age:

9-12 weeks at experimental start

## K. Quarantine:

Minimum 1 day (Animals used in Part 1 and 2 were quarantined for seven days, and animals used in Part 3 were in quarantine for 1 day).

L. Identification method

Upon receipt in the Toxicology Department, each animal received a Q number. At the end of the quarantine period animals were weighed and uniquely identified by a metal ear-tags displaying the animal number (C8419-C8446, C9230, C9232, C9233, C9238-C9240) as documented in the study records. In addition, each cage used for animal housing during the study was identified by individual cage tag (study number, animal number, group number, dose level, species/strain, sex, and study director).

M. Specific housing and maintenance

All but one animal (Q0029) received from Charles River Laboratories were judged to be in good health and suitable as test animals. Female rat #Q0029 was not eating due to malocclusion of the two front teeth and was not included in the randomization part of the study. During quarantine, rats were individually housed in suspended wire-mesh cages. The cages were elevated above Bed-O'Cob® bedding. Upon release from quarantine, rats in Part 2 continued to be housed individually in suspended wire-mesh cages (7"x10"x7"). Rats that were used in Part 1 and 3 were transferred to individual Roth-style glass metabolism cages and allowed to acclimate to this experimental environment prior to administration of test article. Rats that were excluded from the study during the randomization process were returned to the Animal Resources Group.

All animals were housed in the environmentally controlled animal rooms designed to be maintained at 64-79°F, 30-70% relative humidity, 10-15 air changes per hour and 12-hour fluorescent-light/dark cycle. Temperature and humidity in the rooms were monitored twice a day during the week and once per day on weekends. During the conduct of the study, temperature was maintained within the range specified in the protocol (64-79°F). Relative humidity in the rooms was maintained between 30 and 70% with the exceptions described in section: Deviations. Light cycle was only interrupted on the first experimental day of Part 1 (see Deviations) and as necessary to perform study procedures. Air flow and animal condition in the metabolism cages were monitored twice a day (am/pm) during the experiment. Air flow in the metabolism cages was kept in the range of 500-700 ml/min.

A commercial diet of Purina® Certified Rodent Chow #5002 (Lot number SEP 01 99 1A and OCT 24 00 2A) and reverse osmosis water (Edstrom Industries, Inc. Waterford, WI) were available *ad libitum*. Periodic analysis of the certified feed for the presence of heavy metals and pesticides was performed and provided by the manufacturer to ensure that none are present in concentrations that would be expected to affect the outcome of the study. Results of the most recent water analysis that was provided by an independent laboratory (Ann Arbor Technical Services, Ann Arbor, MI) and feed analysis were reviewed by the Study Director. Documentation of study director reviews were placed in the study records. There were no contaminants in the water or feed identified at levels that would interfere with the integrity of the study.

#### N. Method of Euthanasia:

*Part 1.* Immediately prior to euthanasia animals were placed in the pre-weighed anesthesia chambers primed with methoxyflurane and weighed. At the appropriate time points, all animals in mass balance (MB) groups were euthanized by exsanguination *via* cardiac puncture under methoxyflurane anesthesia.

*Part 2 and 3.* Animals in whole body autoradiography (WBA) groups (Part 2) were euthanized by CO<sub>2</sub> asphyxiation. Terminal body weights were collected prior to euthanasia. Animals used in Part 3 (additional dosing experiment) were also euthanized by CO<sub>2</sub> asphyxiation and carcasses were placed in 35% TEAH for solubilization.

## JUSTIFICATION FOR SELECTION OF TEST SYSTEM

The Fischer 344 rats are recognized as an appropriate strain of rats for toxicity studies. The Fischer 344 female and male rat have previously been used in pharmacokinetic and metabolism studies of various silicone materials and data obtained in this study can be used as historical data. The use of both sexes enabled us to detect any potential sex-related differences in absorption of PDMS from the GI tract. The number of animals to be used in Part 1 of the study was selected to provide statistical power (N=4). An additional 6 rats were used in Part 3 (additional experiment) with the intent to substantiate PDMS content in feces by achieving better extraction efficiencies. Based on previous work (4), a minimum number of time points were chosen for the whole-body autoradiography that would allow the visual assessment of the *in vivo* distribution pattern of radioactivity, as well as tracking the transient time of radioactivity in the gastrointestinal tract. Due to the nature of the WBA methodology and unique physicochemical properties of PDMS fluids, it was necessary to include an additional group of eight spare animals (4 females and 4 males) in Part 2 of the study. Spare rats were planned to be processed only if sectioning of rats in the primary group was not successful.

## EXPERIMENTAL DESIGN

The study design was based on the Test Guidelines for metabolism and pharmacokinetics, August 1998 (3). The study consisted of three parts and each part was done as a separate experiment. In part 1, disposition of  $^{14}\text{C}$ -PDMS, 350 cst was evaluated by conducting a mass balance study. In Part 2, *in vivo* tissue distribution of radiolabeled compound and potential metabolites was assessed by using a whole body autoradiography technique. In part 3, the objective was to better understand the behavior of PDMS, 350 cst once it is excreted in feces, and to improve extraction efficiencies in fecal samples.

### 1. Randomization

Rats in Part 1 and 3 of the study were weighed, randomized into test groups using a table of random numbers generated by Microsoft® Excel Versions 7.0 and 9.0. All animals were within  $\pm 20\%$  of the mean body weight for the group to which they were assigned. Rats used in the Part 2 (WBA) were not randomized.

## **2. Organization of Test Groups**

Organization of test groups is presented in Table 1. Part 1 (MB groups) and Part 2 (WBA groups) were performed concurrently and animals were dosed on the same day. The first part consisted of two exposure groups (groups 3 and 4) and two control groups (groups 1 and 2). The second part consisted of 2 exposure groups (groups 5 and 6) with group 6 being used as a spare group. Animals used in Part 3 (additional dosing experiment) were organized in control group 7 and exposure group 8.

## **3. Test Article Preparation and Analysis**

Appropriate volumes of labeled test article were added to unlabeled test article and mixed well to achieve a specific activity which produced a target radioactivity of approximately 40-50 $\mu$ Ci for each animal at a targeted dose of 1000 mg/kg of body weight (BW). The dose of 1000 mg/kg was selected based on EPA recommendations for test substances of low toxicity and on previous toxicology studies that were conducted with PDMS fluids.

In Part 1 and 2 dosing solution was prepared one day prior to use. A verification of the radiochemical purity for the dosing test article was evaluated on the day of preparation and on the day of dosing using HPLC with radiometric detection. Radiochemical purity of the dosing solutions on the day of dosing was 100%. Radioactivity concentration in dosing test article (specific activity) was measured by liquid scintillation analysis on the day of preparation as well as the day of exposure prior to initiation. Specific activity on the day of dosing was 0.26 mCi/g. Difference in specific activities determined on the day of preparation and the day of exposure was calculated as a relative range between the two measurements and was determined to be 2.76%.

In additional Part 3, neat test article was prepared two days prior to use and specific activity on the day of dosing was 0.27 mCi/g. Difference in specific activities determined on the day of preparation and the day of exposure was calculated as a relative range between the two measurements and was determined to be 0.56%. Radiochemical purity of the dosing solutions was 100%. Documentation of these analyses is maintained in the study records. Dosing solutions were stored at  $4 \pm 4^{\circ}\text{C}$ . Any remaining test article was returned to Test Article Characterization group upon completion of the study.

#### **4. Test Article Administration**

##### **A. Animal preparation**

Approximately 24 hours prior to dosing, rats in mass balance groups (1-4) were placed into individual glass metabolism cages for the acclimation. Rats in groups 7 and 8 (additional experiment) were previously acclimated to the glass metabolism cages (11). On the day of dosing all animals were weighed prior to dosing and targeted dose was calculated based on the animal body weight.

##### **B. Dosing**

On the day of dosing all of the test systems, except control animals in groups 1, 2 and 7, were dosed with  $^{14}\text{C}$ -PDMS, 350 cst by oral gavage using a syringe equipped with a stainless steel feeding needle. Administered dose was determined gravimetrically. Actual doses were between 38-54  $\mu\text{Ci}$  per rat and 949-1080 mg PDMS/kg of BW. Individual dosing data are presented in Tables 2, 3 and 4. Animals in control groups were not dosed with any material. Animals in MB groups (1-4) were placed in metabolism cages after dosing and housed for 96 hours. Animals in WBA groups 5 and 6 were returned to the suspended wire-mesh cages after dosing and housed for a maximum of 96 hours. Animals used in additional experiment (control group 7 and exposure group 8) were housed in the individual glass metabolism cages for 72 hours. At the end of the exposure, rats were euthanized as described in the section Test System: N. Method of Euthanasia.

#### **5. Sample Collection**

##### **Mortality/Morbidity/Daily Observations**

All animals were observed in their cages for mortality, morbidity, and signs of distress daily by study personnel through the completion of the in-life phase of the study.

##### **A. Part 1 (mass balance group)**

Immediately following dose administration, animals in the MB Groups were returned to individual glass metabolism cages for collection of urine, feces,  $\text{CO}_2$  and expired air at scheduled times (Table 5). At the same time, animals in control group 1 and 2 were placed in glass metabolism cages for collection of the excreta at the 24 hr time points (Table 5).

### Glass Metabolism Cage Set-up and Operation

A total of 12 glass metabolism cages designed for rats were used in this part of the study. Each cage was set up and operated at target flow rates and conditions for a minimum of 48 hours prior to housing of animals. During this time the system was evaluated for leaks by monitoring flow rates using flow meters and if necessary, appropriate actions were taken to assure the leaks were corrected and the system was sealed.

Roth-style glass metabolism cages were set up and operated in a manner that allows adequate and interrupted airflow. Connections between parts were made using Tygon® tubing. For connections leading from the exhaust side of the chamber, Teflon® lined Tygon® tubing was used.

Room air was drawn through the cages using a vacuum pump. The airflow rate through each chamber was monitored using a calibrated flow meter and was maintained between 500-600 ml per minute. The room air entering the system was passed through a series of Drierite® and Ascerite® canisters designed to remove H<sub>2</sub>O and CO<sub>2</sub>, respectively. Cage temperatures were recorded once in the A.M. and once in the P.M. every day during animal housing in the metabolism cages.

Glass tubes containing charcoal were used for trapping expired volatiles. Urine and feces were collected over dry ice and CO<sub>2</sub> was collected in 4N KOH traps (gas towers). Tissues and remaining carcasses were collected at the sacrifice time points.

### Excreta Collection

#### *Urine*

The Roth style glass metabolism cages that were used have been modified to allow direct collection of urine into 4 oz glass jars. Jars were pre-weighed and labeled with a study number, animal number, group number, sample identity, collection interval, storage conditions and date of collection. While collecting, each jar was maintained on dry ice. At the appropriate time point, the jars containing urine were removed from the cage, capped, and placed in a -80°C freezer for storage and processing.

*Feces*

The Roth-style glass metabolism cages being used were modified to allow direct collection of feces into 4 oz. glass jars. Jars were pre-weighed and labeled with a study number, animal number, group number, sample identity, collection interval, storage conditions and date of collection. While collecting, each jar was maintained on dry ice. At the appropriate time point, the jars were removed from the cage, capped, and placed in  $-80^{\circ}\text{C}$  freezer for storage and processing.

*Expired Air*

Glass tubes containing activated charcoal were used for trapping volatiles in the expired air. Glass tubes were supplied closed at each end and were opened by etching and breaking each end. Each tube was then attached in-line on the exhaust side of the cage. One tube was used per cage per collection interval. Each tube was labeled with a study number, animal number, group number, sample identity, collection interval, storage conditions and date of collection. At the appropriate time point, the charcoal tubes were removed, capped, and transferred to a cold room ( $4 \pm 4^{\circ}\text{C}$ ) for storage and processing.

*Carbon Dioxide*

Cage exhaust air was passed through a glass gas trap filled with 150-200 ml of 4N KOH. Each gas trap was filled with KOH prior to initiation of collections. At the appropriate collection interval, KOH was collected into pre-weighed 8 oz. glass jars labeled with study number, animal number, group number, sample identity, collection interval, storage conditions and date of collection. Jars were capped and transferred into the cold room ( $4 \pm 4^{\circ}\text{C}$ ) for storage and processing.

*Metabolism Cage Rinse*

Each glass metabolism cage was washed using 70 % (v/v) ethanol at the completion of the in life part of the study. Glass jars containing ethanol cage washes, labeled with study number, animal number, group number, sample identity, date of collection and storage conditions were transferred to the cold room ( $4 \pm 4^{\circ}\text{C}$ ) for storage and processing.

*Tissue and Organ Collection*

At the terminal sacrifice time point (96 hour post exposure) blood was collected in MB group *via* open thoracic cardiac puncture under methoxyflurane anesthesia. At that time, liver, perirenal fat, GI tract, kidney, spleen and eyes were collected in the pre-weighed vials that were pre-filled with 35% TEAH and labeled with study number, animal number, group number, sample identity, date of collection and storage conditions. Upon removal, the GI tract was mechanically emptied of its contents by squeezing segments of GI tract with hemostats. GI contents were collected into the empty, labeled and pre-weighed 4 oz. glass jars. In addition, tools used to clean GI tract were rinsed with up to 3 ml of RO water into the jar containing GI contents, as needed and documented in the study records. Remaining carcasses were placed into the pre-weighed jars that were pre-filled with 35% TEAH to be solubilized at room temperature.

*Control animals*

Rats in control groups 1 and 2 (animals not dosed) were housed in glass metabolism cages under the same environmental conditions as animals in the exposure groups. Excreta were collected at the 24 hr time point. At the terminal sacrifice time point (96 hr post-dose), rats in the control groups were euthanized by exsanguination *via* cardiac puncture under methoxyflurane anesthesia and selected tissues and organs were collected as defined in Table 5. Each glass metabolism cage was rinsed with 70% ethanol following removal of the animal.

*B. Part 2 (whole body autoradiography group)*

Immediately after dose administration, animals in the WBA Group were returned to wire-mesh cages for exposure durations of 12, 24, 48 and 96 hours (Table 1). All animals were observed in their cages for mortality, morbidity, and signs of distress daily by study personnel through the completion of the in-life phase of the study.

At specific time points (Table 1) animals in Groups 5 and 6 were weighed and sacrificed by CO<sub>2</sub> asphyxiation, and immediately frozen in a hexane/dry ice bath at approximately -75°C. and stored at -80 ± 10°C. The frozen carcasses from animals of Group 5 were positioned within a frame and embedded in a 4% aqueous solution of carboxymethylcellulose which supported the carcass for sectioning. Blocks were stored at -80°C (± 10°C) until sectioned. Carcasses from Group 6 (spare group) were stored frozen -80°C (± 10°C).

*C. Part 3 (additional experiment)*

A total of 6 glass metabolism cages were set up and operated as described above in a Part 1 with exception that connections leading from the exhaust side of the chamber were made using Teflon<sup>®</sup> tubing.

Immediately following dose administration, animals were returned to individual glass metabolism cages for collection of urine, feces, CO<sub>2</sub> and expired air at scheduled times (Table 5). Animals were euthanized by CO<sub>2</sub> asphyxiation 72 hr post-dose and carcasses were solubilized *in toto* in the pre-weighed amount of 35% TEAH at room temperature. Each glass metabolism cage was rinsed with toluene following removal of the animal.

Control animals

Animals in control group 7 were individually housed in the glass metabolism cages at the same time as the animals in the exposure group 8 for collection of the excreta at the 24-hr time point (Table 5). At the termination of 72 hr, animals were euthanized by CO<sub>2</sub> asphyxiation and carcasses were solubilized *in toto* in the pre-weighed amount of 35% TEAH at room temperature. Each glass metabolism cage was rinsed with toluene following removal of the animal.

## **6. Sample Processing and Analysis**

*A. Part 1 (mass balance group)*

Sample preparations for radioactivity analysis by Liquid Scintillation Counter (LSC) are described below. Feces and GI contents were homogenized using a tissue homogenizer prior to solubilization and extraction.

Aliquots of the blood samples were taken, then solubilized in the Soluene 350: Isopropanol (1:1, v/v) solution, decolorized with 30% hydrogen peroxide and analyzed by LSC for radioactivity content.

Charcoal tubes, that were used to trap expired volatiles, were desorbed with toluene (main and back-up portion combined). Separate aliquots of the toluene were taken for total radioactivity analysis by LSC.

Urine, KOH and cage rinse samples were weighed following collection and aliquots were directly analyzed for radioactivity content by LSC.

Feces and GI contents were kept frozen at  $-80 \pm 10^{\circ}\text{C}$  following collection. Sample processing involved thawing, weighing and homogenizing samples with Milli-Q water at 3:1 v:w water to sample ratio. Aliquots of the fecal and content of GI tract homogenates were taken and solubilized in 35%TEAH, decolorized with hydrogen peroxide and neutralized with isopropanol. At that time, aliquots of the solubilized feces were analyzed by LSC for radioactivity content. Remaining fecal and content of GI tract homogenates were stored at  $-80 \pm 10^{\circ}\text{C}$ . Fecal homogenates from 12, 24 and 48 hour time points had sufficient radioactivity ( $>100,000$  dpm/g homogenate) to be further analyzed by HPLC with radiochemical detection. Aliquots of the fecal homogenates were taken and extracted with tetrahydrofuran (THF) or toluene, and then extracts were analyzed by HPLC with radiochemical detection using a gel-permeation chromatography (GPC) column in order to determine if the radioactivity present in the feces and contents of the GI tract is unchanged  $^{14}\text{C}$ -PDMS. The amount of radioactivity extracted in THF or toluene was compared to the amount of radioactivity found by TEAH solubilization in order to determine feces extraction efficiency. Radioactivity content in fecal extracts and in solubilized feces was determined by liquid scintillation analysis.

The carcasses and tissues (eyes, spleen, kidneys, perirenal fat, liver, GI tract) were solubilized in 35% TEAH immediately after collections. The aliquots of the solubilized tissues were taken, neutralized with 6N hydrochloric acid (HCl) and analyzed by LSC for radioactivity content.

Radioactivity of all the samples was quantified by liquid scintillation analysis (Packard LSC Model 2500TR or 3100 TR). Each sample was counted for 10 minutes or a 2 sigma %value of two, whichever came first. All counts were converted to absolute radioactivity (disintegrations per minute, dpm) by automatic quench correction. Results were corrected for matrix background radioactivity that was determined by using rats in the control groups 1 and 2.

All the samples were stored under following conditions:

KOH, Cage rinses	$4 \pm 4^{\circ}\text{C}$
Charcoal tubes, Toluene extracts	$4 \pm 4^{\circ}\text{C}$
Urine, Feces, GI contents	$-80 \pm 10^{\circ}\text{C}$
Blood	$4 \pm 4^{\circ}\text{C}$
Solubilized carcass and tissues	Ambient

THF Extracts (feces, GI content)	$4 \pm 4^{\circ}\text{C}$
Frozen carcasses (WBA)	$-80 \pm 10^{\circ}\text{C}$

#### Control animals

Samples collected from the control animals (Groups 1 and 2) were processed and analyzed the same as samples from the dosed animals in mass balance groups. Results obtained from control animals were used to determine matrix background levels.

#### *B. Part 2 (whole body autoradiography group)*

Animals from Group 5 were sectioned by placing the frozen block on a stage of a CryoMacrocut® cryomicrotome (Leica, Deerfield, IL) with temperature maintained at approximately  $-25^{\circ}\text{C} \pm 5^{\circ}$ . Parasagittal sections of approximately 40  $\mu\text{m}$  in thickness were collected onto adhesive tape at various levels to include major organs and tissues. Non-dehydrated sections were then mounted on a cardboard support, covered with a layer of plastic wrap, and exposed to Kodak BioMax MR® radiographic film (Eastman Kodak Company, Rochester, NY) at  $-80^{\circ}\text{C}$  for 2, 3 and 4 weeks. At the end of the exposure periods, films were developed on Cordell™ MXR-14 automatic film processor (Cordell, Peabody, MA). The images were digitally acquired from the film with Hewlett-Packard ScanJet (Palo Alto, CA). After the film had been developed, non-dehydrated sections were disposed as radioactive waste. One representative section from each level was dehydrated within the cryochamber for 48 to 72 hours and retained as a reference for comparison with the film.

The original films from each time point of Group 5 were evaluated visually and ranked on a gradient scale with zero as background, low level (+1), moderate (2+ to 3+) and (4+) as highest intensity. Since interpretation of films from the Group 5 was certain and results were clear, no animal from the spare group (Group 6) was processed for evaluation.

#### *C. Part 3 (additional dosing experiment)*

All samples collected in Part 3 were processed and analyzed as described above (Part 1) with the exception of the fecal samples. All fecal samples were processed for analysis on the day of collection (no freezing). Samples were homogenized with Milli-Q water at 3:1 v:w water to sample ratio using tissue homogenizer. Aliquots of the fecal homogenates were taken and solubilized in 35%TEAH, decolorized with hydrogen peroxide and neutralized with isopropanol. At that time, aliquots of the solubilized feces were analyzed by LSC for radioactivity content. At the same time, aliquots from the 12, 24 and 48 fecal homogenates were first extracted 3 times

with toluene, and then fecal sample residues remaining from the toluene extraction were extracted an additional 3 times with THF. Aliquots of the toluene and THF extracts were analyzed for the radioactivity content by LSC, and by HPLC with radiometric detection using a GPC column for a qualitative determination of the toluene/THF extractable radioactivity (Appendix B). In addition, a weighed portion of the remaining extracted fecal residue after double extraction with toluene and THF was removed and solubilized in 35% TEAH and analyzed by LSC to determine any remaining radioactivity that had not been extracted into either toluene or THF.

#### Control animals

Samples collected from the control animals (Group 7) were processed and analyzed the same as samples from the dosed animals (Group 8). Excreta and tissues collected in the control groups were used for matrix background effects.

### 7. *Parameters Measured*

The radioactivity content found in the tissues (blood, fat, eyes, kidney, spleen, liver, GI tract), and in the residual organs and tissues that were left behind in the remaining carcasses of the animals in mass balance groups (groups 1-4), was considered to represent the absorbed portion of the administered dose. The radioactivity found in urine, feces, contents of GI tract, expired air, cage rinse and CO<sub>2</sub> traps represents excreted portion of the administered dose. In addition, fecal extracts were qualitatively assessed using HPLC with radiochemical detection using a GPC column in order to determine if the radioactivity present in the feces is unchanged <sup>14</sup>C-PDMS.

Feces extraction efficiency was determined by comparing the amount of radioactivity extracted from fecal samples to radioactivity recovered by solubilization of fecal samples.

Solubilization processing efficiency was determined in the spiking experiment by comparing the amount of radioactivity used for spiking fecal pellets to the amount of radioactivity recovered after fecal homogenization with water and solubilization in 35% TEAH (Appendix B).

Whole body autoradiography films were visually evaluated for the *in vivo* assessment of tissue distribution of radioactivity and estimation of the transient time through the GI tract.

## **8. Data Analysis**

Radioactivity content in the samples is expressed as  $\mu\text{g}$  PDMS equivalents per gram of specimen and as the percent of the administered dose (Appendix A). Statistical analysis of the data was carried out using Microsoft® Excel™ and SAS®. Values that are below limits of quantification (LOQ) were considered equivalent to zero. The LOQ was defined by matrix background radioactivity and was determined by using animals in control groups. Comparison between males and females in MB groups were made using two-tailed t-test. Statistical significance was evaluated at  $p < 0.05$ . A one-tailed t-test was used to test the hypothesis that the amount of radioactivity in a sample was significantly greater than zero.

## **9. Deviations**

1. Results of the most recent water analysis and manufacturer certificate of feed analysis are maintained with the facility records in HES Archive. Study director review of these documents is included in the study records but copies of these documents are not kept in the study files. This has no impact on the study outcome.
2. Inadvertently, some of the liver and urine weights were inaccurate. These weights were reconstituted from the weights that remained after taking aliquots for LSC analysis. This was considered to have no impact on the study outcome.
3. Feces samples collected at 72 hr from control rats # C8419 and C8420 were cross contaminated during homogenization process. For this timepoint, feces from a spare, non-exposed rat was used to establish background. This was considered to have no impact on the study outcome.
4. A deviation occurred in the protocol with regard to the section IX. C (Environmental conditions). Inadvertently on the first experimental day of Part 1 and 2 (2/17/00) the light switch was not in the timer position causing the light cycle to be approximately 4 hr longer, and dark cycle 4 hr shorter. This was considered to have no impact on the study outcome.
5. A deviation occurred in the protocol with regard to the section IX. C (Environmental conditions). Humidity in the environmentally controlled animal fell below 30% on the first experimental start day (2/17/00). This was considered to have no impact on the study outcome.
6. Randomization of female rats in the MB group was performed using 7 instead of 8 animals. This was considered to have no impact on the study outcome.
7. Inadvertently, Lot number and expiration date of ethanol that was used for cage rinses in Part 1 was not recorded. This was considered to have no impact on the study outcome.

8. Roth-style glass metabolism cages were run for approximately 42 hrs instead of 48 hrs as stated in the protocol to verify the vacuum source. This was considered to have no impact on the study outcome.

## RESULTS AND DISCUSSION

This study was designed to provide disposition data for test article, radiolabeled  $^{14}\text{C}$ -PDMS (supplied as Dow Corning™ 200 Fluid), viscosity 350 cst. A single dose of the neat test article was orally administered to four female and four male Fischer 344 rats in mass balance (MB) groups (group 3 and 4) and to eight female and eight male rats in whole body autoradiography (WBA) groups (group 5 and 6). Two rats of each sex (group 1 and 2) were not dosed and were used as MB controls. Excreta and tissues collected in the control groups were used for matrix background effects. In order to qualitatively determine the profile of radioactivity present in feces and confirm PDMS content in feces, additional work was performed to improve fecal extraction efficiencies.

An additional 6 rats (2 females and 2 males were dosed, 1 female and 1 male as controls were not dosed) were used in Part 3 of the study. A targeted dose of 1000mg/kg body weight was calculated based on the animal body weight. Actual doses were determined gravimetrically and the average dose administered to female and male rats in MB groups was 1025.2 and 999.5 mg/kg of body weight, respectively (Table 2). In the WBA groups average of the administered dose was 1018.4 and 983.3 mg/kg BW for female and male rats, respectively (Table 3). In the additional dosing experiment, the average of the administered dose was 1054.2 and 1032.5 mg/kg BW for female and male rats, respectively (Table 4). Rats in all the exposure groups received between 38 and 54  $\mu\text{Ci}$  per animal.

Housing the MB animals in the Roth-style glass metabolism cages for 96 hours after administration of neat test article *via* oral gavage (Part 1) enabled assessment of the total radioactivity recovery. Excreta were collected at the predetermined time points (Table 5). At the completion of the in life part each glass metabolism cage was rinsed with 70% ethanol to remove possible traces of PDMS from excreta that were left behind in the metabolism cages. Toluene was used for rinsing glass metabolism cages instead of 70 % ethanol in the additional dosing experiment, because 70 % ethanol was considered to be potentially inadequate solvent for PDMS, 350 cst (8). Airflow and animal condition in the metabolism cages were monitored twice a day (am/pm) during the experiment.

Evaluation of the mass balance of radioactivity following oral administration of  $^{14}\text{C}$ -PDMS, 350 cst demonstrated that virtually all of the orally administered  $^{14}\text{C}$ -PDMS, 350 cst was rapidly excreted. Only traces of radioactivity, if any, were recovered in tissues and carcasses that remained after tissue harvesting 96 hour post dosing (Table 6: 0.004% and 0.001% of administered dose in females and males, respectively). As also shown in Table 6, the total dose recovery in females was 93.613 % and in males 97.424 %, with 93.609% and 97.403 % of administered dose excreted, respectively. Resulting radioactivity excretion and overall dose recovery was significantly greater in males than in females. Nearly all of excreted test article was found in feces. Data presented in Table 7 show that 99.98% of the total recovered dose was found in feces and only low levels of radioactivity, if any, were recovered from urine (less than 0.02% of administered and total recovered dose). Presented percent dose recoveries in feces, and consequent overall recoveries, were corrected for the solubilization processing efficiency, which was determined to be 92% in a spiking experiment (Appendix B, Attachment D). In this experiment, fecal samples were spiked with  $^{14}\text{C}$ -PDMS, 350 cst and stored frozen overnight at  $-80^{\circ}\text{C}$  prior to processing (homogenization and solubilization) to mimic typical study conditions. Some initial loss of radioactivity might be attributed to PDMS migration from the feces samples and binding to the glass of collection jars during frozen storage. This behavior has been seen with another hydrophobic siloxane, e.g. octamethylcyclotetrasiloxane (12). Also, loss of radioactivity to the glass might occur during sample homogenization in an aqueous environment followed by transfer of homogenate aliquots into new vials for solubilization.

The bulk of fecal elimination occurred during first 48 hours after dosing (Table 8, Figure 1). This course of fecal excretion was consistent among rats in all the groups. After 72 hours only small amounts of radioactivity ( $< 0.2\%$  of administered dose) and after 96 hours only traces of radioactivity ( $< 0.01\%$  of administered dose) were recovered in feces of all the rats in MB groups (Appendix A). This quantitative assessment of PDMS excretion was supported by qualitative assessment of PDMS excretion using whole body autoradiography (Figures 2 and 3).

Original films were evaluated visually (Appendix D). Figures in this report are scanned images of the original autoradiographs. As shown in Figures 2 and 3, twelve and 24 hours after dosing radioactivity appeared to be concentrated in the contents of GI tract (small intestines, cecum and colon) in both females and males. There was a small amount of radioactivity noted in the residual contents of the stomach. A small amount of radioactivity was noted on the ventral and dorsal surface of the rats as possible contamination on their coats by the test article. There was no disposition of radioactivity noted in any other organs or tissues. At 48 hours in both female and

male rats, radioactivity appeared to be limited to the GI tract but concentration levels were notably decreased (Figures 2 & 3). Low amounts were noted in the small intestine and cecum with a moderate amount in the colon. No radioactivity was noted in any other organs or tissues. At 96 hours after dose, there appeared to be total elimination of  $^{14}\text{C}$ - PDMS, 350 since no radioactivity was observed in either of the animals.

To qualitatively determine the profile of radioactivity present in feces, aliquots of the 12, 24 and 48 hour fecal homogenates were extracted with tetrahydrofuran (THF) and analyzed by HPLC with radiometric detection using a gel permeation column (Appendix B). Radioactivity levels of GI contents at 96 hr and feces samples collected at 6, 72 and 96 hr were not sufficient to be analyzed by HPLC with radiochemical detection. The amount of radioactivity extracted with THF was compared to the amount of radioactivity found by liquid scintillation analysis of the solubilized fecal homogenates in order to determine the extraction efficiency. The resulting extraction efficiencies averaged 77%, 85%, and 73% for 12, 24, and 48 hour fecal homogenate extracts, respectively. The results of HPLC analyses of the 12, 24 and 48 hour fecal samples gave similar radioactivity profiles as a solvent standard of PDMS, 350 cst as well as matrix standards spiked with PDMS, 350 cst (extracts of spiked control fecal homogenates) indicating that no detectable metabolites or degradation products were present in feces following single administration of PDMS, 350 cst. Example radio-chromatograms of a 12 hour male, 12 hour female, and a QC fecal homogenate THF extracts are presented in figure 4. Due to the less than optimum extraction efficiencies found with the THF extractions for the QC samples (78% of amount spiked) in addition to study samples (average range 73-85% of radioactivity found by solubilization), method development work was initiated to try to find a more suitable extraction solvent. It was determined, as a result of this method development work that extraction of QC samples with toluene resulted in better extraction efficiencies. In fact, extraction efficiencies of QC samples ran in parallel with study samples extracted in toluene were 95%. However, the extraction of study samples in toluene after two freeze thaw cycles resulted in low extraction efficiencies (Average range 50-81% of radioactivity found by original solubilization) and continued to decrease after prolonged storage and three freeze-thaw cycles during sample processing. Nevertheless, solubilization efficiencies after 3 freeze-thaw cycles remained the same as compared to original solubilization data. Based on these results, it was presumed that the loss of PDMS upon extraction was either due to un-extractable binding to the fecal components or to freeze-thaw cycles and degradation of the PDMS to polar products that are un-extractable with toluene.

As a result of additional bioanalytical work, a new dosing experiment (Part 3) was conducted with the intention of eliminating possible loss due to prolonged frozen storage and freeze-thaw cycles and improving fecal extraction efficiencies using both THF and toluene for extraction. Feces samples from 12, 24 and 48 hour time points were processed on the day of collection. Fecal homogenates were extracted three times in toluene followed by additional three times in THF. Extraction with toluene gave average of 77% extraction efficiency, and extraction with THF gave an additional average of 14%. Total extraction in two solvents has an average of 92 % when compared to the solubilization data (Appendix B, Attachment E). Solubilization of the residue from the dual extraction gave only additional average of 1% remaining unextracted. HPLC/Radiometric analysis of Toluene/THF extracts showed that both extracts analyzed separately contained only unchanged PDMS, 350 cst (Appendix B). These results showed that extraction of PDMS, 350 cst from feces obtained from dosed animals could be done quantitatively with a two-solvent extraction and confirmed complete excretion of PDMS, 350 cst in the unchanged form.

## SUMMARY OF RESULTS

1. The majority of the orally administered  $^{14}\text{C}$ -PDMS, 350 cst was recovered over 96 hour post-administration period. Dose recovery in female rats was 93.61% and in male rats 97.42% (Recoveries were corrected for solubilization processing efficiency).
2. Nearly all of the recovered dose was excreted in the feces (99.98% of recovered dose);
3. All of the radioactivity present in feces was attributed to the unchanged PDMS, 350 cst. No detectable degradation products were present in feces.
4. No radioactivity was detected in tissues and organs by whole body autoradiography at 96 hours post-dose. Less than 0.005% of administered dose was detected in tissues and carcasses by liquid scintillation analysis at 96 hour post-dose.
5. Whole body autoradiography data at 12, 24 and 48 hours post dosing showed that radioactivity was concentrated in the contents of the GI tract. No radioactivity was detected outside the GI tract with the exception of small exterior contamination.
6. Both sexes showed comparatively similar pattern of disposition at each time point.

## CONCLUSION

Both mass balance and whole body autoradiography data suggest that  $^{14}\text{C}$ -PDMS, 350 cst was rapidly excreted in the feces unchanged following oral administration with little if any absorption.

## ARCHIVE

Study related records, inclusive of, but not limited to, study authorization, study correspondence, study protocol (including amendments and deviations), the study schedule, signatures of the study personnel involved in the conduct of the study, test article documentation, test system records, observation records, equipment verification and condition records, dosing records, sample collection records, sample preparation records, analytical data, Excel worksheets, and the final report, will be maintained in the archives of Dow Corning Corporation, Health and Environmental Sciences, Midland, MI.

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Table 1. Organization of Test Groups

	Group <sup>1)</sup>	Group ID	Sex	Number of animals	Target dose (mg / kg BW)	Exposure duration (hr)
PART 1	1	Control <sup>1</sup> (MB)	F	2	0	96 <sup>1</sup>
	2	Control <sup>1</sup> (MB)	M	2	0	96 <sup>1</sup>
	3	MB	F	4	1000	96
	4	MB	M	4	1000	96
PART 2	5A	WBA	1F, 1M	2	1000	12
	5B	WBA	1F, 1M	2	1000	24
	5C	WBA	1F, 1M	2	1000	48
	5D	WBA	1F, 1M	2	1000	96
PART 2 (reserve)	6A	WBA	1F, 1M	2	1000	12
	6B	WBA	1F, 1M	2	1000	24
	6C	WBA	1F, 1M	2	1000	48
	6D	WBA	1F, 1M	2	1000	96
PART 3 <sup>2</sup>	7	Additional exp. (Controls) <sup>1</sup>	1F, 1M	2	0	72 <sup>1</sup>
	8	Additional exp.	2F, 2M	4	1000	72

<sup>1)</sup>Animals in control groups were not dosed and were housed in metabolism cages for 72-96 hours.

<sup>2)</sup> Additional experiment (Part 3) conducted to improve PDMS extraction from feces samples.

MB = Mass Balance; BW = Body Weight

WBA = Whole body autoradiography

Table 2. Individual Dosing Data: Part 1 (Mass Balance Groups)

Animal ID <sup>1)</sup>	Group	Sex	Body weight (g)	Dose/rat (mg)	Dose/rat (µCi)	<sup>14</sup> C-PDMS neat (mg/kg BW)
C8421	3	F	145.0	149.3	38.8	1029.7
C8422	3	F	147.7	159.5	41.5	1079.9
C8423	3	F	149.2	151.1	39.3	1012.7
C8424	3	F	149.5	146.3	38.0	978.6
C8427	4	M	176.1	186.8	48.6	1060.8
C8428	4	M	175.0	173.8	45.2	993.1
C8429	4	M	190.7	185.1	48.1	970.6
C8430	4	M	192.7	187.6	48.8	973.5

<sup>1)</sup> Rats in the control groups 1 and 2 were not dosed.

Average dose of PDMS, 350 cst administered via oral gavage to female and male rats was 1025.2 and 999.5 mg per kg of body weight, respectively.

Table 3. Individual Dosing Data: Part 2 (Whole Body Autoradiography)

Animal ID	Group	Sex	Body weight (g)	Dose/rat (mg)	Dose/rat (mCi)	<sup>14</sup> C-PDMS neat (mg/kg BW)
C8431	5A	F	149.7	151.4	39.36	1011.4
C8435	5A	M	189.9	184.5	47.97	971.6
C8432	5B	F	146.8	145.6	37.86	991.8
C8436	5B	M	198.3	196.8	51.17	992.4
C8433	5C	F	155.4	151.8	39.47	976.8
C8437	5C	M	193.6	183.7	47.76	948.9
C8434	5D	F	160.1	165.7	43.08	1035.0
C8438	5D	M	196.1	193.2	50.23	985.2
C8439	6A	F	151.9	160.4	41.70	1056.0
C8443	6A	M	195.4	187.5	48.75	959.6
C8440	6B	F	145.1	149.6	38.90	1031.0
C8444	6B	M	191.7	190.7	49.58	994.8
C8441	6C	F	155.7	157.4	40.92	1010.9
C8445	6C	M	191.4	186.7	48.54	975.4
C8442	6D	F	155.3	160.6	41.76	1034.1
C8446	6D	M	187.7	194.9	50.67	1038.4

Average dose of PDMS, 350 cst administered via oral gavage to female and male rats was 1018.4 and 983.3 mg per kg of body weight, respectively.

Table 4. Individual Dosing Data: Part 3 (Additional experiment)

Animal ID <sup>1)</sup>	Group	Sex	Body weight (g)	Dose/rat (mg)	Dose/rat (μCi)	<sup>14</sup> C-PDMS neat (mg/kg BW)
C9230	8	M	202.1	207.2	53.87	1025.24
C9232	8	M	193.3	201.0	52.26	1039.83
C9238	8	F	160.7	168.7	43.86	1049.78
C9239	8	F	160.4	169.8	44.15	1058.60

<sup>1)</sup> Rats in the control group 7 were not dosed.

Average dose of PDMS, 350 cst administered via oral gavage to female and male rats was 1054.2 and 1032.5 mg per kg of body weight, respectively.

Table 5. Sample Collection Time Points

Groups	Exposure duration (hr)	Expired air (hr)	Urine (hr)	Feces (hr)	CO <sub>2</sub> (hr)	Tissues <sup>1)</sup> / Carcasses (hr)
1, 2 (Control)	0	24, 48, 72, 96	24, 48, 72, 96	24, 48, 72, 96	24, 48, 72, 96	96*
3, 4	96	6, 12, 24, 48, 72, 96	6, 12, 24, 48, 72, 96	6, 12, 24, 48, 72, 96	24, 48, 72, 96	96*
7 (Control)	0	24	24	24	24	72 * 2)
8	72	24, 48, 72	24, 48, 72	12, 24, 48, 72	24, 48, 72	72 * 2)

\* Sacrifice time points

<sup>1)</sup> Tissues collected in Part 1: blood, eyes, spleen, kidneys, perirenal fat, liver, GI tract, carcass<sup>2)</sup> No tissues collected in Part 3, carcasses solubilized *in toto*

**Table 6. Disposition of Radioactivity in Female and Male Fischer 344 Rats Following Oral Administration of Neat <sup>14</sup>C-PDMS, 350 cst**

Percent of Administered Dose  $\pm$  Standard Error of the Mean

N/ Sex	Time (hr)	Average Dose (mg/kg BW)	Excreted <sup>1), 4)</sup> (%)	Recovered in tissues <sup>2)</sup> (%)	Recovered in carcasses (%)	Total Recovered <sup>4)</sup> (%)
Group 3 4/ F	96	1025.22	93.609 $\pm$ 0.720	0.001 $\pm$ 0.000	0.003 $\pm$ 0.001	93.613 $\pm$ 0.720
Group 4 4/ M	96	999.52	97.423 $\pm$ 0.581	0.001 $\pm$ 0.000	0.000 <sup>3)</sup>	97.424 $\pm$ 0.581

<sup>1)</sup> As defined in Table 7.

<sup>2)</sup> Tissues collected at the sacrifice time point (96 hr post exposure) : blood, eyes, perirenal fat, spleen, kidneys, liver and GI tract emptied from it's contents.

<sup>3)</sup> Not greater than zero based on One-tailed T test (see Appendix C)

<sup>4)</sup> Percent dose recovered in feces was corrected for the fecal sample processing efficiency (92%)

**Table 7. Disposition of Excreted\* Radioactivity in Female and Male Fischer 344 Rats Following Oral Administration of Neat  $^{14}\text{C}$ -PDMS, 350 cst**

Percent of Administered Dose  $\pm$  Standard Error of the Mean

N/ Sex	Time (hr)	Urine	Content of GI tract	Cage rinse	CO <sub>2</sub> (KOH)	Expired air	Feces <sup>2)</sup>	Total Excreted* <sup>1)</sup> <sup>2)</sup>	Total Dose Recovery <sup>2)</sup>	Feces (% of total recovered dose)
4 / F	96	0.012 $\pm$ 0.001	0.001 $\pm$ 0.000	0.00 <sup>1)</sup>	0.00 <sup>1)</sup>	0.002 $\pm$ 0.001	93.594 $\pm$ 0.720	93.609 $\pm$ 0.720	93.613 $\pm$ 0.720	99.98
4 / M	96	0.016 $\pm$ 0.000	0.00 <sup>1)</sup>	0.001 $\pm$ 0.000	0.001 $\pm$ 0.000	0.003 $\pm$ 0.000	97.403 $\pm$ 0.582	97.423 $\pm$ 0.581	97.424 $\pm$ 0.581	99.98

\* Excreted radioactivity = Percent of administered dose recovered in urine, feces, contents of GI tract, CO<sub>2</sub> (KOH traps), expired air (charcoal tubes) and cage rinses.

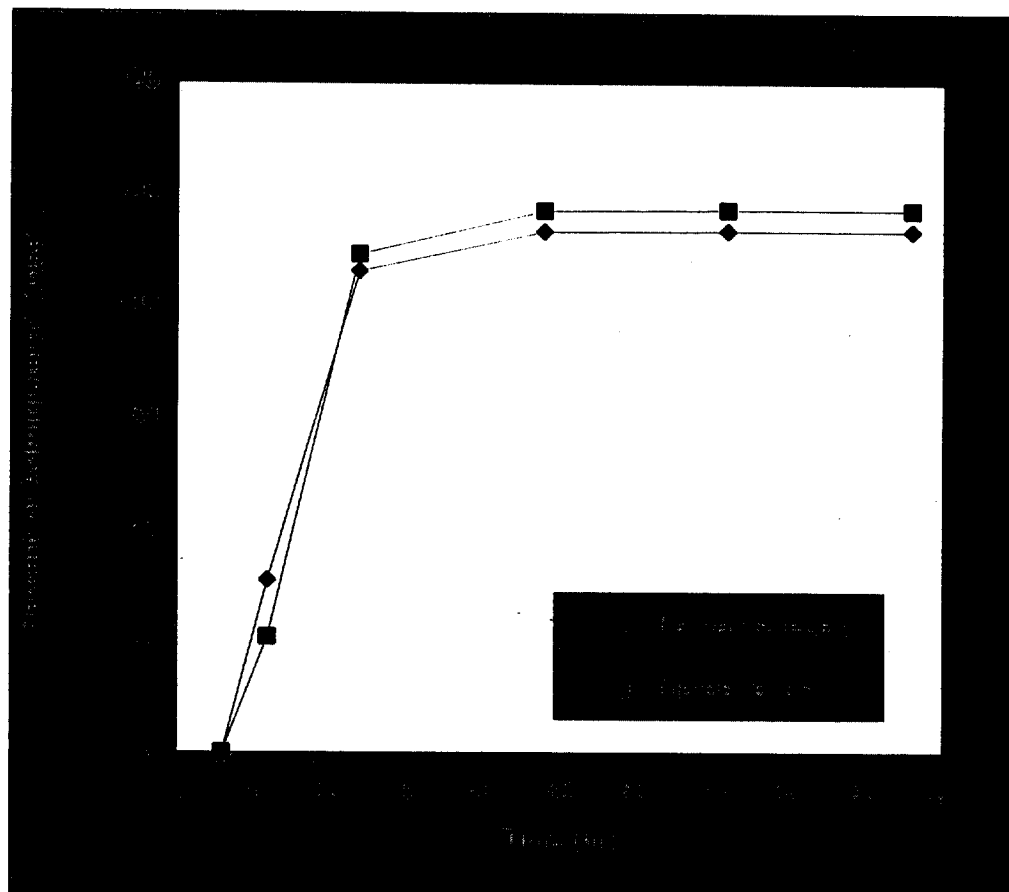
<sup>1)</sup> Not greater than zero based on One-tailed T test (see Appendix C)

<sup>2)</sup> Percent dose recovered in feces, and consequently percent dose excreted and total dose recovery, were corrected for the fecal sample processing efficiency (92%).

Table 8. Excretion of  $^{14}\text{C}$ -PDMS, 350 cst in feces over timePercent of Administered Dose  $\pm$  Standard Error of the Mean

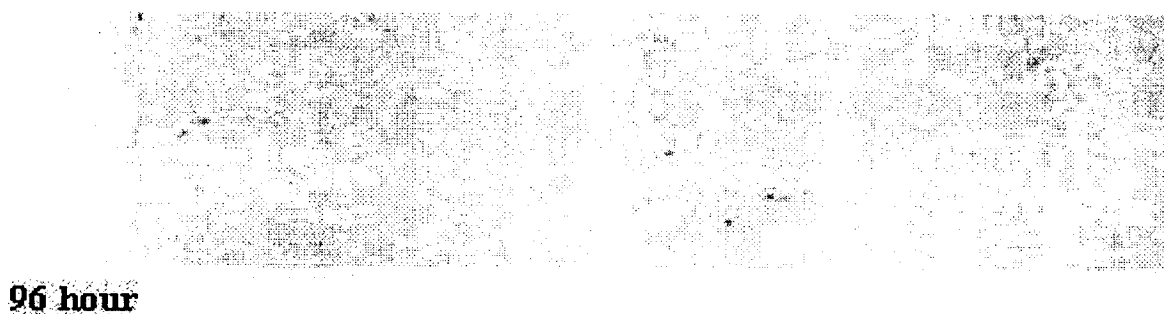
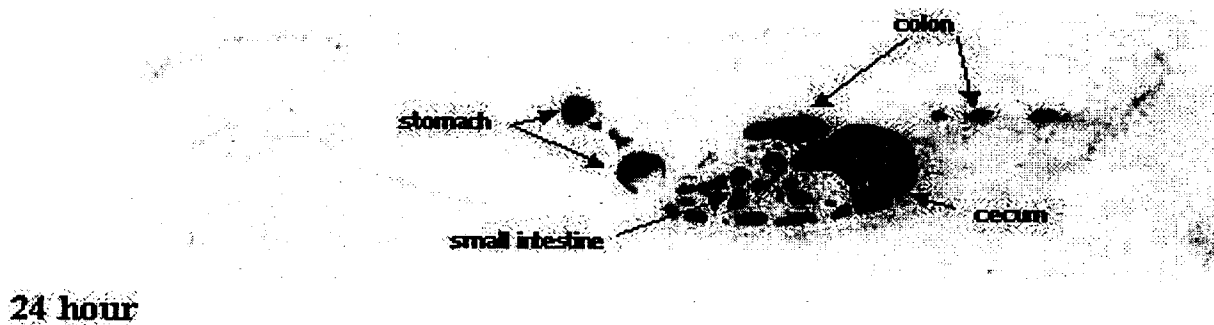
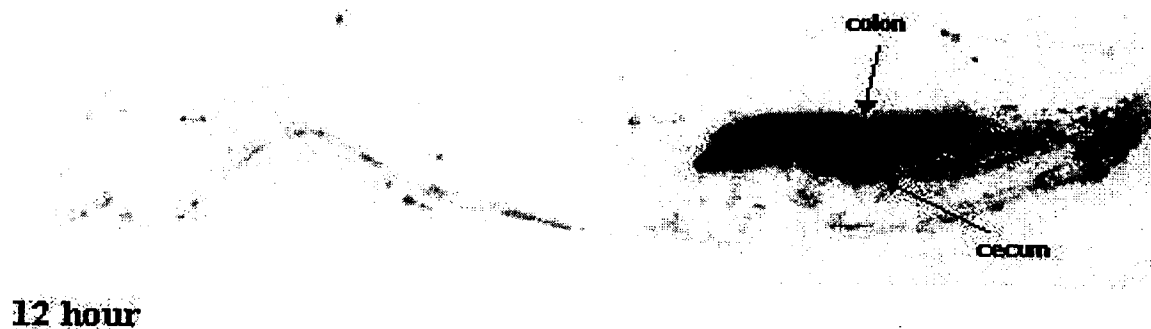
Rat ID	Sex	Time 6 hr	Average % dose in feces	Time 12 hr	Average % dose in feces	Time 24 hr	Average % dose in feces	Time 48 hr	Average % dose in feces	Time 72 hr	Average % dose in feces	Time 96 hr	Average % dose in feces
C8421	F	0.000		21.562		82.181		93.221		93.463		93.482	
C8422	F	0.000		42.133		87.932		92.196		92.253		92.254	
C8423	F	0.000		1.708		82.580		92.880		93.020		93.024	
C8424	F	0.000	0.000 $\pm$ 0.000	58.140	30.886 $\pm$ 12.273	92.851	86.386 $\pm$ 2.523	95.516	93.453 $\pm$ 0.720	95.613	93.587 $\pm$ 0.720	95.617	93.594 $\pm$ 0.720
C8427	M	0.000		14.882		83.755		95.634		95.887		95.900	
C8428	M	0.000		31.645		87.492		97.426		97.549		97.559	
C8429	M	0.000		30.693		96.360		98.709		98.733		98.738	
C8430	M	0.000	0.000 $\pm$ 0.000	5.764	20.746 $\pm$ 6.302	89.908	89.378 $\pm$ 2.649	97.042	97.203 $\pm$ 0.633	97.409	97.395 $\pm$ 0.584	97.415	97.403 $\pm$ 0.582

Percent dose recovered in feces was corrected for the sample processing efficiency (92%)

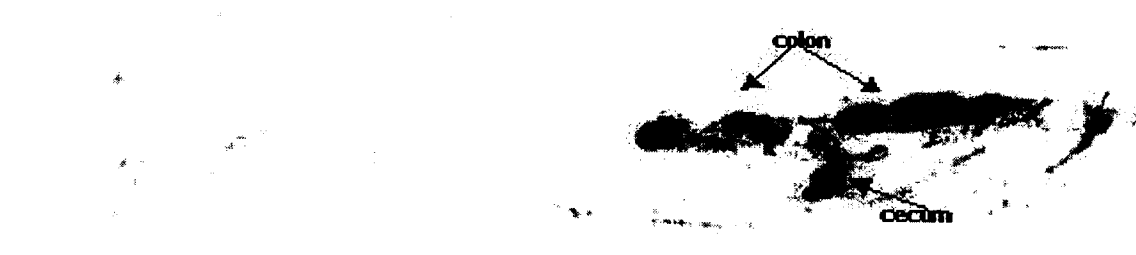
**Figure 1. Fecal Excretion of Radioactivity Associated with  $^{14}\text{C}$ -PDMS, 350 cst**

\* Percent dose recovered in feces was corrected for sample processing efficiency (92%)

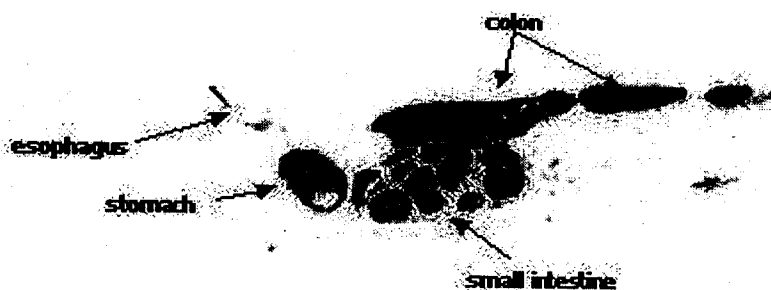
**Figure 2 . Whole Body Autoradiography of Female Fischer 344 Rat**  
**12, 24, 48 and 96 hr Post Exposure**



**Figure 3. Whole Body Autoradiography of Male Fischer 344 Rat**  
**12, 24, 48 and 96 hr Post Exposure**



**12 hour**

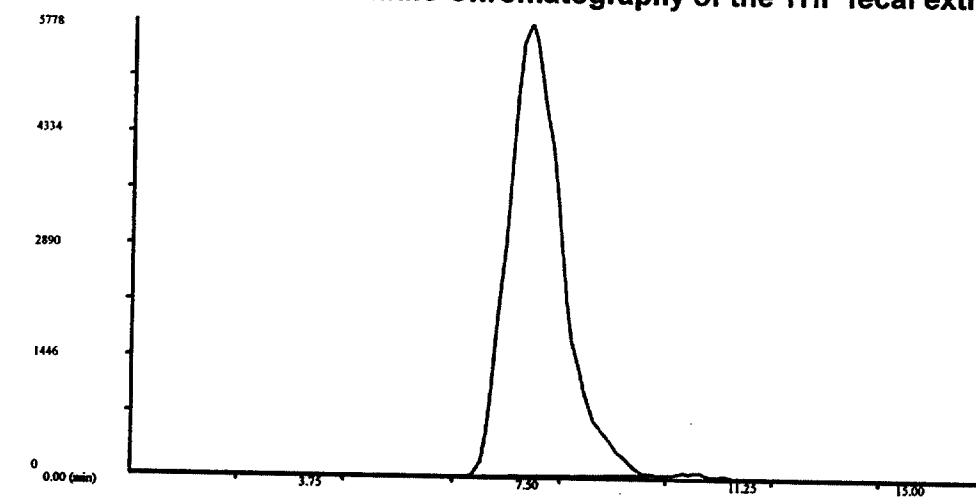
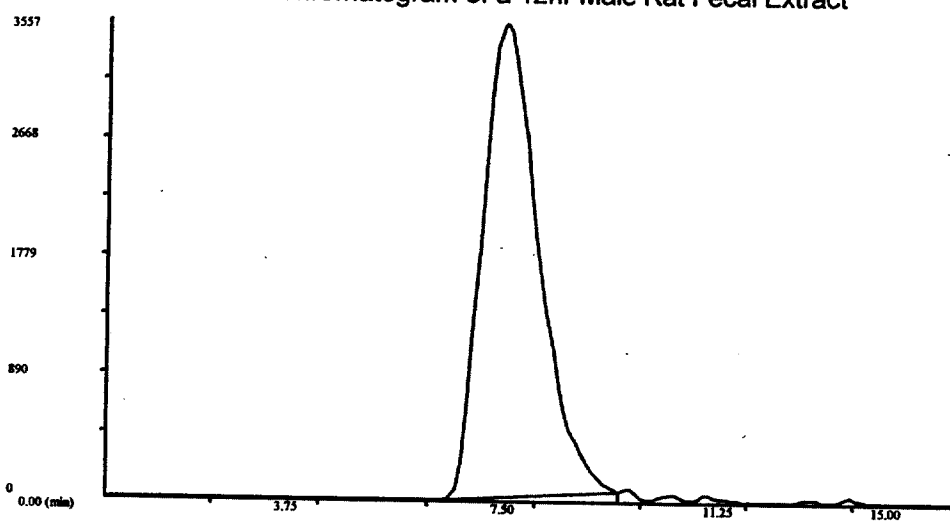
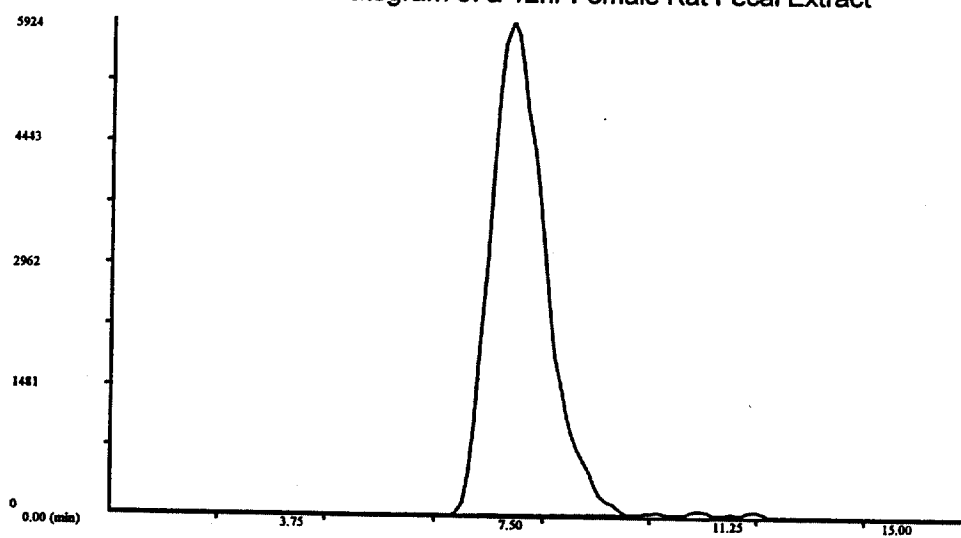


**24 hour**



**48 hour**

**96 hour**

**Figure 4. Gel Permeation-Radio Chromatography of the THF fecal extracts****GPC Radio-Chromatogram of a 12hr Male Rat Fecal Extract****GPC Radio-Chromatogram of a 12hr Female Rat Fecal Extract****GPC Radio-Chromatogram of a  $^{14}\text{C}$ -PDMS, 350cSt, Spiked Control Fecal Extract**

## Calculations and Abbreviations

### Calculations

**1. Radioactivity**

$$1 \mu\text{Ci} = 2.22 \times 10^6 \text{ DPMs}$$

**2. Specific activity of dosing solution:**

$$\text{DPM/mg of dosing solution} / 2.22 \times 10^6 (\text{DPM}/\mu\text{Ci}) = \mu\text{Ci/mg in dosing solution}$$

**3. Dose (DPMs):**

$$\text{S.A. of dosing solution (DPMs/mg)} \times \text{dose (mg)} = \text{DPMs}$$

**4. Dose ( $\mu\text{Ci}$ )**

$$\text{S.A. of dosing solution } (\mu\text{Ci/mg}) \times \text{dose (mg)} = \mu\text{Ci}$$

**5. Matrix Background**

Average DPM/g of control samples

**7. Radioactivity concentration in the sample aliquots (Corrected DPM/g)**

$$\text{Aliquot DPM/Aliquot Wt.(g)} - \text{matrix background (DPM/g)}$$

**8. Total DPMs in the sample:**

$$\text{Radioactivity conc. (DPM/g)} \times \text{Sample wt.}^* (\text{g}) = \text{DPMs}$$

\*sample wt. = homogenate wt.(e.g. feces), extract wt. (e.g. charcoal) or direct sample wt. (e.g. urine)

**9. Percent Dose:**

$$\frac{\text{Total DPMs in sample}}{\text{Dose (DPMs)}} \times 100 = \% \text{ Dose}$$

**10. Average Percent Dose**

Percent dose for the group of test systems

**11. Cumulative Percent Dose in excreta**

Percent of administered dose collected in excreta added to the percent of the administered dose of the previous timepoint to get the total percent recovery in urine, feces,  $\text{CO}_2$  and expired air over duration of exposure.

**12. Correction for solubilization processing efficiency (92%)**

$$\text{Percent of administered dose recovered in feces} \times 100 / 92$$

**13. Percent of the total recovery**

Percent of administered dose recovered in the sample (e.g. excreta)  $\times 100 / \text{Total \% dose recovered in all the samples.}$

**14. Equivalent  $\mu\text{g}$  PDMS**

Total DPM in the sample\* / specific activity of PDMS (DPM/mg PDMS) \*1000  
( $\mu\text{g}/\text{mg}$ )

\*sample = homogenate ( e.g. feces), extract (e.g. charcoal) or direct sample (e.g. urine, KOH)

#### 15. Equivalent $\mu\text{g}$ PDMS/g of specimen

Total DPM in the sample\* / specific activity of PDMS (DPM/mg) \*1000  $\mu\text{g}/\text{mg}$  /  
specimen\*\* weight (g)

\*sample = homogenate ( e.g. feces), extract (e.g. charcoal) or direct sample (e.g. urine, KOH)

\*\*specimen = tissue, extract (charcoal), or excreta (e.g. feces, urine)

#### 16. Equivalent $\mu\text{g}$ PDMS in blood/rat

$\mu\text{g}$  Eq. PDMS/g of blood X Body Weight (kg) X 57.2865 g blood/kg BW

#### 17. Data analysis

One-tailed t-test was used to test the hypothesis that amount of percent radioactivity recovered in samples was significantly greater than zero. If the amount of recovered radioactivity was not significantly greater than zero, reported values were zero for individual samples (Appendix A) and Group averages (Appendix A, Tables 5 and 6).

#### 18. Reanalysis Criteria (%RR)

The %RR is derived by calculating the difference between two values (DPM/g) and expressing this difference as a percentage of the mean for the two values (aliquots). Samples which fail to meet the following criteria shall be re-analyzed in duplicate:

- A) For DPM/g between 0 and 299 the %RR must be less than or equal to 20. (F1)
- B) For DPM/g between 300 and 999 the %RR must be less than or equal to 15. (F2)
- C) For DPM/g greater than 1000, the %RR must be less than 10%. (F3)

An exception to the above criteria is when the % dose recovered in the sample is less than or equal to 0.1%, than no re-analysis of a sample is required, failure to meet criteria 1-3 notwithstanding.

Counts in bold letters are repeats due to non-uniformity of the sampling.

#### Abbreviations:

DPM = Disintegrations per minute

Sol'n. = Solution

Rep. = Replicate

LSC = Liquid Scintillation Counter

Wt. = Weight

Eq./Equiv. = Equivalent

THF = Tetrahydrofuran

Bkg. = Background

N.A. = Not applicable

N.D. = Not determined

LOQ = Limit of quantification

THF = Tetrahydrofuran

Conc. = concentration

F = flag indicating non-uniformity of the sampling

Counts in bold letters are repeats.

Avg. = Average

S.A. = Specific Activity

WBA = Whole Body Autoradiography

GI tract = Gastrointestinal Tract

St.Dev. = Standard Deviation

SEM = Standard error of the mean

TEAH = Tetraethylammonium hydroxide

N.S. = No sample

B.W. = Body weight

BLQ = Below limit of quantification

PDMS = Polydimethylsiloxane

Cum = cumulative

Hr. = hour

Homog., Homogen. = Homogenate



Animal ID	Time Pt.	Group/ Sex	Vial Tare Wt.(g)	Tare + Sample Wt.(g)	Sample (extract) Wt.(g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eq/g sample	Dose (mg)	Dose (DPM)	% Dose	Cum dose	% RR	F
C8421	24hr	3/F	17.2318	30.6467	13.4149	0.1812	49	270.42	167.82	154.70	2075	0.27	149.3	86175960	0.002	0.003	16.96	
C8421	24hr	3/F	17.2318	30.6467	13.4149	0.1761	43	244.18	141.58	154.70	2075	0.27	149.3	86175960	0.002	0.003	16.96	
C8422	24hr	3/F	17.3321	30.7541	13.422	0.1737	36	207.25	104.65	104.17	1398	0.18	159.5	92063400	0.002	0.002	0.91	
C8422	24hr	3/F	17.3321	30.7541	13.422	0.1745	36	206.30	103.70	104.17	1398	0.18	159.5	92063400	0.002	0.002	0.91	
C8423	24hr	3/F	17.1998	30.6242	13.4244	0.1754	24	136.83	34.23	40.61	545	0.07	151.1	87214920	0.001	0.001	31.44	
C8423	24hr	3/F	17.1998	30.6242	13.4244	0.1738	26	149.60	46.99	40.61	545	0.07	151.1	87214920	0.001	0.001	31.44	
C8424	24hr	3/F	17.1810	30.5312	13.3502	0.1746	21	120.27	17.67	15.10	202	0.03	146.3	84444360	0.000	0.000	33.99	
C8424	24hr	3/F	17.1810	30.5312	13.3502	0.1737	20	115.14	12.54	15.10	202	0.03	146.3	84444360	0.000	0.000	33.99	
C8427	24hr	4/M	17.2073	30.5452	13.3379	0.1732	49	282.91	192.75	192.83	2572	0.33	186.8	107820960	0.002	0.004	0.08	
C8427	24hr	4/M	17.2073	30.5452	13.3379	0.1731	49	283.07	192.91	192.83	2572	0.33	186.8	107820960	0.002	0.004	0.08	
C8428	24hr	4/M	17.1766	30.5804	13.4038	0.1753	33	188.25	98.09	101.78	1364	0.18	173.8	100317360	0.001	0.002	7.25	
C8428	24hr	4/M	17.1766	30.5804	13.4038	0.1738	34	195.63	105.47	101.78	1364	0.18	173.8	100317360	0.001	0.002	7.25	
C8429	24hr	4/M	17.2972	30.6615	13.3643	0.1761	32	181.71	91.55	83.74	1119	0.15	185.1	106839720	0.001	0.002	18.65	
C8429	24hr	4/M	17.2972	30.6615	13.3643	0.1746	29	166.09	75.93	83.74	1119	0.15	185.1	106839720	0.001	0.002	18.65	
C8430	24hr	4/M	17.2425	30.8472	13.4047	0.1749	45	257.29	167.13	179.29	2403	0.31	187.6	108282720	0.002	0.003	13.56	
C8430	24hr	4/M	17.2425	30.8472	13.4047	0.1740	49	281.61	191.45	179.29	2403	0.31	187.6	108282720	0.002	0.003	13.56	
C8419	48hr	1/F	17.2099	30.6032	13.3933	0.1747	17	97.31	NA	NA	NA	NA	0	0	NA	NA	NA	
C8419	48hr	1/F	17.2099	30.6032	13.3933	0.1745	18	103.15	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	48hr	1/F	17.2654	30.6178	13.3524	0.1748	15	85.81	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	48hr	1/F	17.2654	30.6178	13.3524	0.1734	18	103.81	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	48hr	2/M	17.3391	30.7780	13.4389	0.1751	16	91.38	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	48hr	2/M	17.3391	30.7780	13.4389	0.1731	18	103.99	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	48hr	2/M	17.1961	30.5939	13.3978	0.1737	17	97.87	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	48hr	2/M	17.1961	30.5939	13.3978	0.1748	17	97.25	NA	NA	NA	NA	0	0	NA	NA	NA	
C8421	48hr	3/F	17.1610	30.5615	13.4005	0.1742	25	143.51	45.99	48.82	654	0.08	149.3	86175960	0.001	0.003	11.58	
C8421	48hr	3/F	17.1610	30.5615	13.4005	0.1743	26	149.17	51.65	48.82	654	0.08	149.3	86175960	0.001	0.003	11.58	
C8422	48hr	3/F	17.2638	30.6090	13.3452	0.1726	19	110.08	12.56	14.73	197	0.03	159.5	92063400	0.000	0.002	29.43	
C8422	48hr	3/F	17.2638	30.6090	13.3452	0.1748	20	114.42	16.90	14.73	197	0.03	159.5	92063400	0.000	0.002	29.43	
C8423	48hr	3/F	17.2808	30.6789	13.3981	0.1723	19	110.27	12.75	6.58	88	0.01	151.1	87214920	0.000	0.001	187.65	
C8423	48hr	3/F	17.2808	30.6789	13.3981	0.1736	17	97.93	0.41	6.58	88	0.01	151.1	87214920	0.000	0.001	187.65	
C8424	48hr	3/F	17.1302	30.5128	13.3826	0.1741	18	103.39	5.87	5.96	80	0.01	146.3	84444360	0.000	0.000	3	
C8424	48hr	3/F	17.1302	30.5128	13.3826	0.1738	18	103.57	6.05	5.96	80	0.01	146.3	84444360	0.000	0.000	3	
C8427	48hr	4/M	17.2048	30.6084	13.4036	0.1737	31	178.47	80.85	66.67	894	0.12	186.8	107820960	0.001	0.004	42.53	
C8427	48hr	4/M	17.2048	30.6084	13.4036	0.1732	26	150.12	52.49	66.67	894	0.12	186.8	107820960	0.001	0.004	42.53	
C8428	48hr	4/M	17.1772	30.5403	13.3631	0.1740	25	143.88	46.06	40.65	543	0.07	173.8	100317360	0.001	0.003	26.58	
C8428	48hr	4/M	17.1772	30.5403	13.3631	0.1731	23	132.87	35.25	40.65	543	0.07	173.8	100317360	0.001	0.003	26.58	
C8429	48hr	4/M	17.1477	30.5202	13.3725	0.1740	21	120.69	23.07	17.13	229	0.03	185.1	106839720	0.000	0.002	69.28	
C8429	48hr	4/M	17.1477	30.5202	13.3725	0.1746	19	108.82	11.20	17.13	229	0.03	185.1	106839720	0.000	0.002	69.28	
C8430	48hr	4/M	17.2825	30.7035	13.421	0.1743	22	126.22	28.60	26.08	350	0.05	187.6	108282720	0.000	0.003	19.34	
C8430	48hr	4/M	17.2825	30.7035	13.421	0.1733	21	121.18	23.56	26.08	350	0.05	187.6	108282720	0.000	0.003	19.34	
C8419	72hr	1/F	17.1994	30.6061	13.4067	0.1738	20	115.07	NA	NA	NA	NA	0	0	NA	NA	NA	
C8419	72hr	1/F	17.1994	30.6061	13.4067	0.1731	15	86.66	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	72hr	1/F	17.2427	30.6237	13.381	0.1747	17	97.31	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	72hr	1/F	17.2427	30.6237	13.381	0.1721	14	81.35	NA	NA	NA	NA	0	0	NA	NA	NA	

Animal ID	Time Pt.	Group/ Sex	Vial Tare Wt.(g)	Tare + Sample Wt.(g)	Sample (extract) Wt.(g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eq/g sample	Dose (mg)	Dose (DPM) % Dose	Cum % dose	% RR	F
C8425	72hr	2/M	17.3064	30.7529	13.4465	0.1745	16	91.69	NA	NA	NA	NA	0	0	NA	NA	
C8425	72hr	2/M	17.3064	30.7529	13.4465	0.1729	17	98.32	NA	NA	NA	NA	0	0	NA	NA	
C8426	72hr	2/M	17.1904	30.6068	13.4164	0.1734	14	80.74	NA	NA	NA	NA	0	0	NA	NA	
C8426	72hr	2/M	17.1904	30.6068	13.4164	0.1748	17	97.25	NA	NA	NA	NA	0	0	NA	NA	
C8421	72hr	3/F	17.2274	30.5775	13.3501	0.1763	16	90.75	0.00	1.02	14	0.00	149.3	86175960	0.000	0.004	200
C8421	72hr	3/F	17.2274	30.5775	13.3501	0.1750	17	97.14	2.05	1.02	14	0.00	149.3	86175960	0.000	0.004	200
C8422	72hr	3/F	17.3209	30.6893	13.3684	0.1744	17	97.48	2.38	4.40	59	0.01	159.5	92063400	0.000	0.002	91.89
C8422	72hr	3/F	17.3209	30.6893	13.3684	0.1773	18	101.52	6.43	4.40	59	0.01	159.5	92063400	0.000	0.002	91.89
C8423	72hr	3/F	17.1752	30.5726	13.3974	0.1736	17	97.93	2.83	3.08	41	0.01	151.1	87214920	0.000	0.001	16.54
C8423	72hr	3/F	17.1752	30.5726	13.3974	0.1727	17	98.44	3.34	3.08	41	0.01	151.1	87214920	0.000	0.001	16.54
C8424	72hr	3/F	17.2886	30.7276	13.4399	0.1742	17	97.59	2.49	2.32	31	0.00	146.3	84444360	0.000	0.000	14.41
C8424	72hr	3/F	17.2886	30.7276	13.4399	0.1748	17	97.25	2.16	2.32	31	0.00	146.3	84444360	0.000	0.000	14.41
C8427	72hr	4/M	17.2418	30.6166	13.3748	0.1751	16	91.38	0.00	0.00	0	0.00	186.8	107820960	0.000	0.004	#DIV/0!
C8427	72hr	4/M	17.2418	30.6166	13.3748	0.1747	16	91.59	0.00	0.00	0	0.00	186.8	107820960	0.000	0.004	#DIV/0!
C8428	72hr	4/M	17.2377	30.6538	13.4161	0.1745	19	108.88	16.88	19.81	266	0.03	173.8	100317360	0.000	0.003	29.59
C8428	72hr	4/M	17.2377	30.6538	13.4161	0.1743	20	114.74	22.74	19.81	266	0.03	173.8	100317360	0.000	0.003	29.59
C8429	72hr	4/M	17.1862	30.6028	13.4166	0.1745	17	97.42	5.42	8.40	113	0.01	185.1	106839720	0.000	0.003	71.01
C8429	72hr	4/M	17.1862	30.6028	13.4166	0.1741	18	103.39	11.39	8.40	113	0.01	185.1	106839720	0.000	0.003	71.01
C8430	72hr	4/M	17.1502	30.5508	13.4006	0.1753	17	96.98	4.98	2.49	33	0.00	187.6	108282720	0.000	0.003	200
C8430	72hr	4/M	17.1502	30.5508	13.4006	0.1737	15	86.36	0.00	2.49	33	0.00	187.6	108282720	0.000	0.003	200
C8419	96hr	1/F	17.2028	30.6458	13.443	0.1753	20	114.09	NA	NA	NA	NA	0	0	NA	NA	
C8419	96hr	1/F	17.2028	30.6458	13.443	0.1761	16	90.86	NA	NA	NA	NA	0	0	NA	NA	
C8420	96hr	1/F	17.2298	30.6158	13.386	0.1748	15	85.81	NA	NA	NA	NA	0	0	NA	NA	
C8420	96hr	1/F	17.2298	30.6158	13.386	0.1735	18	103.75	NA	NA	NA	NA	0	0	NA	NA	
C8425	96hr	2/M	17.2353	30.6383	13.403	0.1741	15	86.16	NA	NA	NA	NA	0	0	NA	NA	
C8425	96hr	2/M	17.2353	30.6383	13.403	0.1743	16	91.80	NA	NA	NA	NA	0	0	NA	NA	
C8426	96hr	2/M	17.1443	30.5277	13.3834	0.1744	19	108.94	NA	NA	NA	NA	0	0	NA	NA	
C8426	96hr	2/M	17.1443	30.5277	13.3834	0.1743	16	91.80	NA	NA	NA	NA	0	0	NA	NA	
C8421	96hr	3/F	17.1957	30.6132	13.4175	0.1752	15	85.62	0.00	0.00	0	0.00	149.3	86175960	0.000	0.004	#DIV/0!
C8421	96hr	3/F	17.1957	30.6132	13.4175	0.1741	15	86.16	0.00	0.00	0	0.00	149.3	86175960	0.000	0.004	#DIV/0!
C8422	96hr	3/F	17.1307	30.5076	13.3769	0.1738	18	103.57	4.94	4.24	57	0.01	159.5	92063400	0.000	0.002	33.31
C8422	96hr	3/F	17.1307	30.5076	13.3769	0.1762	18	102.16	3.53	4.24	57	0.01	159.5	92063400	0.000	0.002	33.31
C8423	96hr	3/F	17.3527	30.7825	13.4298	0.1739	16	92.01	0.00	0.00	0	0.00	151.1	87214920	0.000	0.001	#DIV/0!
C8423	96hr	3/F	17.3527	30.7825	13.4298	0.1760	15	85.23	0.00	0.00	0	0.00	151.1	87214920	0.000	0.001	#DIV/0!
C8424	96hr	3/F	17.2076	30.6370	13.4294	0.1756	18	102.51	3.88	1.94	26	0.00	146.3	84444360	0.000	0.001	200
C8424	96hr	3/F	17.2076	30.6370	13.4294	0.1759	16	90.96	0.00	1.94	26	0.00	146.3	84444360	0.000	0.001	200
C8427	96hr	4/M	17.3666	30.8114	13.4448	0.1745	19	108.88	14.21	8.48	114	0.01	186.8	107820960	0.000	0.005	135.18
C8427	96hr	4/M	17.3666	30.8114	13.4448	0.1745	17	97.42	2.75	8.48	114	0.01	186.8	107820960	0.000	0.005	135.18
C8428	96hr	4/M	17.2252	30.6651	13.4399	0.1754	14	79.82	0.00	0.00	0	0.00	173.8	100317360	0.000	0.003	#DIV/0!
C8428	96hr	4/M	17.2252	30.6651	13.4399	0.1751	16	91.38	0.00	0.00	0	0.00	173.8	100317360	0.000	0.003	#DIV/0!
C8429	96hr	4/M	17.2561	30.6540	13.3979	0.1750	18	102.86	8.18	4.09	55	0.01	185.1	106839720	0.000	0.003	200
C8429	96hr	4/M	17.2561	30.6540	13.3979	0.1753	15	85.57	0.00	4.09	55	0.01	185.1	106839720	0.000	0.003	200
C8430	96hr	4/M	17.2491	30.6807	13.4316	0.1747	18	103.03	8.36	10.52	141	0.02	187.6	108282720	0.000	0.003	40.99
C8430	96hr	4/M	17.2491	30.6807	13.4316	0.1770	19	107.34	12.67	10.52	141	0.02	187.6	108282720	0.000	0.003	40.99

Dosing sol. S.A.		0.28	µCi/mg=	577200	DPM/mg	BKG=		149	BKG=		151	DPM/g		Female 48hr	BKG=		128	DPM/g		Female 72hr	BKG=		145	DPM/g		Female 96hr	BKG=		124	DPM/g		Male 96hr			
BKG= 165		DPM/g		F, 24hr		BKG=		149		BKG=		151		DPM/g		Female 48hr		BKG=		DPM/g		Female 72hr		BKG=		DPM/g		Female 96hr		BKG=		DPM/g		Male 96hr	
BKG= 167		DPM/g		M, 24hr		BKG=		151		BKG=		151		DPM/g		Male 48hr		BKG=		DPM/g		Male 72hr		BKG=		DPM/g		Male 96hr		BKG=		DPM/g		Male 96hr	
FECES																																			
Animal Time		Tare		Tare +		Feces Wt.		Feces Wt.		Water Wt.		Homog. Wt		Rep. Wt.		Rep. Wt.		Conc.		DPM/s/g		DPM/s/g		DPM/s/g		DPM/s/g		DPM/s/g		DPM/s/g		DPM/s/g		DPM/s/g	
ID		Pt		Group		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)		Wt.(g)	
C8421	6hr	3	97.5200	98.4449	0.9249	101.9067	4.3867	0.2247	31	137.96	0.00	0.00	0.00	149.3	86175960	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8421	6hr	3	97.5200	98.4449	0.9249	101.9067	4.3867	0.2291	33	144.04	0.00	0.00	0.00	149.3	86175960	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8422	6hr	3	98.3396	98.9749	1.6353	104.6748	6.3352	0.2266	33	145.63	0.00	0.00	0.00	159.5	92063400	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8422	6hr	3	98.3396	98.9749	1.6353	104.6748	6.3352	0.2447	34	138.96	0.00	0.00	0.00	159.5	92063400	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8423	6hr	3	97.3853	98.9114	1.6261	103.3664	5.9811	0.2318	30	129.42	0.00	0.00	0.00	151.1	87214820	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8423	6hr	3	97.3853	98.9114	1.5261	103.3664	5.9811	0.2126	34	160.00	0.00	0.00	0.00	151.1	87214820	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8424	6hr	3	97.4765	98.0336	0.5541	99.8768	2.1973	0.2302	32	139.01	0.00	0.00	0.00	187.6	108282720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8424	6hr	3	97.4765	98.0336	0.5541	99.8768	2.1973	0.2388	33	138.19	0.00	0.00	0.00	187.6	108282720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8427	6hr	4	96.8969	97.962	1.2651	101.5220	4.8251	0.2395	34	141.96	0.00	0.00	0.00	186.8	107820960	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8427	6hr	4	96.8969	97.962	1.2651	101.5220	4.8251	0.2316	35	180.99	0.00	0.00	0.00	186.8	107820960	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8428	6hr	4	97.3875	98.8558	1.4883	102.9475	5.6000	0.2408	29	120.43	0.00	0.00	0.00	173.8	100317360	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8428	6hr	4	97.3875	98.8558	1.4883	102.9475	5.6000	0.2449	32	130.87	0.00	0.00	0.00	173.8	100317360	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8429	6hr	4	97.0951	97.8948	0.5997	99.2765	2.1804	0.2273	33	145.18	0.00	0.00	0.00	185.1	106839720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8429	6hr	4	97.0951	97.8948	0.5997	99.2765	2.1804	0.2316	34	146.80	0.00	0.00	0.00	185.1	106839720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8430	6hr	4	96.7164	99.4313	2.7149	107.2536	10.5372	0.2266	34	160.78	0.00	0.00	0.00	187.6	108282720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8430	6hr	4	96.7164	99.4313	2.7149	107.2536	10.5372	0.2686	31	150.78	0.00	0.00	0.00	187.6	108282720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8421	12hr	3	98.4549	99.7101	1.2552	103.4976	5.0427	0.2263	784275	3486842.95	3485478.07	3485478.07	3485478.07	149.3	86175960	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8421	12hr	3	98.4549	99.7101	1.2552	103.4976	5.0427	0.2296	761061	3314725.61	3314560.73	3314560.73	3314560.73	149.3	86175960	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8422	12hr	3	97.2849	100.3928	3.1079	106.2491	11.9642	0.2108	648878	3086881.21	3086518.33	3086518.33	3086518.33	159.5	92063400	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8422	12hr	3	97.2849	100.3928	3.1079	106.2491	11.9642	0.2171	628968	2897033.63	2868688.74	2868688.74	2868688.74	159.5	92063400	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8423	12hr	3	98.1623	98.6123	0.4800	99.8658	1.7135	0.2116	164704	778374.29	778209.41	778209.41	778209.41	151.1	87214820	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8423	12hr	3	98.1623	98.6123	0.4800	99.8658	1.7135	0.2096	169727	821624.69	821359.80	821359.80	821359.80	151.1	87214820	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8424	12hr	3	98.0028	100.7800	2.7572	106.8905	10.8877	0.2132	877041	4113700.75	4113636.87	4113636.87	4113636.87	146.3	84444360	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8424	12hr	3	98.0028	100.7800	2.7572	106.8905	10.8877	0.2239	936742	4183761.67	4183598.79	4183598.79	4183598.79	146.3	84444360	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8427	12hr	4	98.1985	98.4407	1.2422	103.0598	4.8613	0.2428	742654	3058706.76	3058636.33	3058636.33	3058636.33	186.8	107820960	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8427	12hr	4	98.1985	98.4407	1.2422	103.0598	4.8613	0.2474	745873	3014848.40	3014678.98	3014678.98	3014678.98	186.8	107820960	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8428	12hr	4	97.3168	98.9434	1.6236	103.7957	6.4759	0.2390	1082719	4530206.02	4530037.60	4530037.60	4530037.60	173.8	100317360	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8428	12hr	4	97.3168	98.9434	1.6236	103.7957	6.4759	0.2322	1042596	4490077.52	4489910.10	4489910.10	4489910.10	173.8	100317360	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8429	12hr	4	98.8293	100.5994	1.7701	105.5715	6.7422	0.2365	1040920	44071353.07	4401185.84	4401185.84	4401185.84	186.1	106839720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8429	12hr	4	98.8293	100.5994	1.7701	105.5715	6.7422	0.2327	1058397	4548332.62	4548185.20	4548185.20	4548185.20	185.1	106839720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8430	12hr	4	97.9448	99.7103	1.7655	104.8802	6.9354	0.2202	198904	893751.14	893583.71	893583.71	893583.71	187.6	108282720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8430	12hr	4	97.9448	99.7103	1.7655	104.8802	6.9354	0.2358	179780	782425.78	782268.38	782268.38	782268.38	187.6	108282720	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8419	24hr	1	97.1532	101.6227	4.4096	114.6814	17.5282	0.2296	37	161.15	0.00	0.00	0.00	0	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00		
C8419																																			

Animal ID	Time	Tare Group	Tare Wt(g)	Tare +		Feces + RO		Homog Wt (g)	Rep. Wt (g)	Rep. (g)	Conc. DPM's/g	DPM's/g corrected	Total DPM in homog.	Conc. ug Eq/g feces	Dose (mg)	Dose (DPM)	% Dose	Cum. % dose	% RR	F
				Feces Wt. (g)	Water Wt. (g)															
C8421	24hr	3	97.9200	99.9859	2.0659	106.1739	8.2539	0.1892	1159234	5848009.28	5848044.40	5822631.74	48059420	40303.51	149.3	86175960	55.769	75.606	0.89	
C8421	24hr	3	97.9200	99.9859	2.0659	106.1739	8.2539	0.1620	939079	5796783.95	5796819.07	5822631.74	48059420	40303.51	149.3	86175960	55.769	75.606	0.89	
C8422	24hr	3	98.6344	101.4921	2.8577	109.8456	11.2112	0.2384	811276	3402998.16	3402998.28	3402998.16	3402998.16	23517.70	159.5	92063400	42.138	80.898	3.31	
C8422	24hr	3	98.6344	101.4921	2.8577	109.8456	11.2112	0.2281	802338	3517483.66	3517318.88	3460076.48	38791809	23517.70	159.5	92063400	42.138	80.898	3.31	
C8423	24hr	3	97.1376	98.6135	2.3769	107.3615	10.2239	0.2335	1475859	6320695.28	6320430.41	6346882.15	64898988	47317.58	151.1	87214920	74.402	75.974	0.83	
C8423	24hr	3	97.1376	98.6135	2.3769	107.3615	10.2239	0.2438	1553959	6320695.28	6320695.28	6346882.15	64898988	47317.58	151.1	87214920	74.402	75.974	0.83	
C8424	24hr	3	98.7635	101.3102	2.5487	108.8558	10.0923	0.2273	618136	2719472.06	2718307.18	2871981.63	26996440	18345.08	146.3	84444360	31.934	85.423	3.54	
C8424	24hr	3	98.7635	101.3102	2.5487	108.8558	10.0923	0.2290	601084	2824820.96	2824868.08	2871981.63	26996440	18345.08	146.3	84444360	31.934	85.423	3.54	
C8427	24hr	4	100.1162	102.8355	2.8193	110.9448	10.8284	0.1944	1233793	6346871.81	6346894.39	6309210.89	68318659	41982.83	186.8	107820980	63.363	77.054	1.18	
C8427	24hr	4	100.1162	102.8355	2.8193	110.9448	10.8284	0.1698	1065900	6272084.81	6271917.38	6309210.89	68318659	41982.83	186.8	107820980	63.363	77.054	1.18	
C8428	24hr	4	99.5302	102.5774	3.0472	111.5782	12.0480	0.2085	874367	4234222.76	4234055.34	4278044.56	51541881	29304.41	173.8	100317360	51.379	80.493	2.06	
C8428	24hr	4	99.5302	102.5774	3.0472	111.5782	12.0480	0.2008	867988	4232201.20	4232033.77	4278044.56	51541881	29304.41	173.8	100317360	51.379	80.493	2.06	
C8429	24hr	4	99.2980	103.8350	4.5370	117.4870	18.1890	0.1944	698075	3590920.78	3590753.38	3548588.24	64545272	24647.30	185.1	106839720	60.413	88.651	2.38	
C8429	24hr	4	99.2980	103.8350	4.5370	117.4870	18.1890	0.1983	660291	3506590.56	3506423.13	3548588.24	64545272	24647.30	185.1	106839720	60.413	88.651	2.38	
C8430	24hr	4	100.3378	105.4516	5.1138	120.0721	19.7343	0.2399	1028732	4276884.86	4276497.44	4247633.32	83824070	28398.71	187.6	108282720	77.412	82.715	1.31	
C8430	24hr	4	100.3378	105.4516	5.1138	120.0721	19.7343	0.2367	988859	4219836.83	4219786.21	4247633.32	83824070	28398.71	187.6	108282720	77.412	82.715	1.31	
C8419	48hr	1	96.4429	104.2864	4.8435	119.2487	19.8058	0.2028	33	182.72	182.72	NA	NA	NA	0	0	NA	NA	NA	
C8419	48hr	1	96.4429	104.2864	4.8435	119.2487	19.8058	0.2119	37	174.61	174.61	NA	NA	NA	0	0	NA	NA	NA	
C8420	48hr	1	96.7671	105.0550	5.2979	121.0629	21.3068	0.2161	28	129.57	129.57	NA	NA	NA	0	0	NA	NA	NA	
C8420	48hr	1	96.7671	105.0550	5.2979	121.0629	21.3058	0.2153	28	130.05	130.05	NA	NA	NA	0	0	NA	NA	NA	
C8425	48hr	2	96.5501	113.1437	13.5936	151.4119	51.8618	0.2266	32	136.37	136.37	NA	NA	NA	0	0	NA	NA	NA	
C8425	48hr	2	96.5501	113.1437	13.5936	151.4119	51.8618	0.1933	30	155.20	155.20	NA	NA	NA	0	0	NA	NA	NA	
C8426	48hr	2	98.6515	107.0304	8.3789	130.8447	32.1932	0.1669	31	185.74	185.74	NA	NA	NA	0	0	NA	NA	NA	
C8426	48hr	2	98.6515	107.0304	8.3789	130.8447	32.1932	0.2086	26	124.64	124.64	NA	NA	NA	0	0	NA	NA	NA	
C8421	48hr	3	96.4203	105.2251	5.8048	122.5253	23.1050	0.1645	63380	388288.75	385139.52	378824.44	8752739	2612.34	149.3	86175960	10.157	86.763	3.33	
C8421	48hr	3	96.4203	105.2251	5.8048	122.5253	23.1050	0.2317	86345	372658.81	372509.37	378824.44	8752739	2612.34	149.3	86175960	10.157	86.763	3.33	
C8422	48hr	3	99.5476	109.2834	9.7358	137.0647	37.5171	0.2066	19888	96263.31	96114.07	96263.31	96263.31	159.5	159.5	92063400	3.923	84.820	0.3	
C8422	48hr	3	99.5476	109.2834	9.7358	137.0647	37.5171	0.2281	21831	96554.82	96405.38	96263.31	96263.31	159.5	159.5	92063400	3.923	84.820	0.3	
C8423	48hr	3	99.4241	103.501	4.0769	118.5888	19.1645	0.2349	100831	429250.74	429101.51	431252.86	8284745	3512.15	151.1	87214920	9.476	85.450	1	
C8423	48hr	3	99.4241	103.501	4.0769	118.5888	19.1645	0.2423	105050	433553.45	433404.21	431252.86	8284745	3512.15	151.1	87214920	9.476	85.450	1	
C8424	48hr	3	98.2438	104.5284	5.2826	122.3123	23.0685	0.2009	18038	89785.96	89636.72	89781.58	2070685	679.10	146.3	84444360	2.452	87.875	0.28	
C8424	48hr	3	98.2438	104.5284	5.2826	122.3123	23.0685	0.2243	20195	90035.87	89888.43	89781.58	2070685	679.10	146.3	84444360	2.452	87.875	0.28	
C8427	48hr	4	98.6888	105.9136	6.2248	124.4580	24.7692	0.1885	90176	476397.27	476238.03	475760.78	11784214	3279.81	186.8	107820980	10.929	87.984	1.04	
C8427	48hr	4	98.6888	105.9136	6.2248	124.4580	24.7692	0.2159	102215	473438.78	473285.54	475760.78	11784214	3279.81	186.8	107820980	10.929	87.984	1.04	
C8428	48hr	4	99.5855	109.2981	9.7106	134.9849	35.3964	0.1936	60764	262210.74	262059.51	256008.64	9168750	1635.83	173.8	100317360	9.140	88.632	2.36	
C8428	48hr	4	99.5855	109.2981	9.7106	134.9849	35.3964	0.2110	64039	256109.00	255957.77	256008.64	9168750	1635.83	173.8	100317360	9.140	88.632	2.36	
C8429	48hr	4	99.4141	108.4797	7.0656	127.6631	28.2490	0.2222	18380	82628.28	82477.02	81743.64	2306176	566.22	185.1	106839720	2.161	90.812	1.79	
C8429	48hr	4	99.4141	108.4797	7.0656	127.6631	28.2490	0.2316	18797	81161.49	81010.25	81743.64	2306176	566.22	185.1	106839720	2.161	90.812	1.79	
C8430	48hr	4	98.1580	106.9991	7.8431	130.9415	31.7855	0.2070	49392	223971.01	223819.78	223589.78	7109912	1599.88	187.6	108282720	6.563	89.278	0.21	
C8430	48hr	4	98.1580	106.9991	7.8431	130.9415	31.7855	0.2139	47809	223591.99	223359.75	223589.78	7109912	1599.88	187.6	108282720	6.563	89.278	0.21	
control	72hr	1						0.2018	26	128.64	128.64	NA	NA	NA	0	0	NA	NA	NA	
control	72hr	1						0.2117	27	127.54	127.54	NA	NA	NA	0	0	NA	NA	NA	
C8425	72hr	2	99.2505	112.0770	12.8265	149.9478	50.8973	0.2268	39	172.72	172.72	NA	NA	NA	0	0	NA	NA	NA	
C8425	72hr	2	99.2505	112.0770	12.8265	149.9478	50.8973	0.2459	36	148.40	148.40	NA	NA	NA	0	0	NA	NA	NA	
C8426	72hr	2	98.8400	106.7425	6.9025	130.7810	30.9410	0.1921	27	166.56	166.56	NA	NA	NA	0	0	NA	NA	NA	



Tare +  
Feces + RO

Animal ID	Time	Pl.	Group	Tare Wt.(g)	Feces Wt. (g)	Feces Wt. (g)	Water Wt. (g)	Homog.Wt (g)	Rep. Wt. (g)	Rep. Wt. (g)	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g in homog.	Total DPM	Conc. ug feces	Dose (mg)	Dose (DPM) 0	% Dose	Cum. dose	% RR	F
C8428	72hr	2	96	8400	106.7426	7.2932	126.1328	28.9273	0.2063	29	140.57	6678.83	6639.94	192076	45.63	149.3	86175960	0.223	85.986	1.2	
C8421	72hr	3	96	2055	106.4987	7.2932	126.1328	28.9273	0.2436	1481	6808.01	6678.83	6639.94	192076	45.63	149.3	86175960	0.223	85.986	1.2	
C8422	72hr	3	96	0679	106.8527	7.5848	130.0080	30.9401	0.2154	397	1843.08	1714.89	1567.84	48503	11.08	159.5	92063400	0.053	84.873	18.79	
C8422	72hr	3	96	0679	106.8527	7.5848	130.0080	30.9401	0.2357	365	1549.58	1420.39	1567.84	48503	11.08	159.5	92063400	0.053	84.873	18.79	
C8423	72hr	3	100	4820	105.5808	5.0988	123.5784	23.0964	0.2018	996	4935.58	4807.39	4860.71	112265	38.15	151.1	87214920	0.129	85.579	2.19	
C8423	72hr	3	100	4820	105.5808	5.0988	123.5784	23.0964	0.2132	1075	5042.21	4814.02	4860.71	112265	38.15	151.1	87214920	0.129	85.579	2.19	
C8424	72hr	3	96	4865	106.1176	6.9511	127.1511	27.8846	0.2093	567	2709.03	2580.84	2580.84	75105	19.56	146.3	84444360	0.089	87.984	9.73	
C8424	72hr	3	96	4865	106.1176	6.9511	127.1511	27.8846	0.2082	619	2973.10	2844.91	2712.88	75105	19.56	146.3	84444360	0.089	87.984	9.73	
C8427	72hr	4	97	7637	105.2925	7.5288	126.2727	28.5090	0.1393	1274	9145.73	8989.16	8908.03	251051	57.77	186.8	107820960	0.233	88.216	4.16	
C8427	72hr	4	97	7637	105.2925	7.5288	126.2727	28.5090	0.1909	1676	8779.47	8622.61	8908.03	251051	57.77	186.8	107820960	0.233	88.216	4.16	
C8428	72hr	4	97	4626	106.4248	8.9622	132.3228	34.8602	0.1640	626	3402.17	3245.61	3255.29	113480	21.94	173.8	100317360	0.113	89.745	0.59	
C8429	72hr	4	96	3825	106.9668	7.5843	129.8346	30.4521	0.1345	129	959.11	802.54	762.31	23214	5.30	185.1	106839720	0.022	90.834	10.56	
C8429	72hr	4	96	3825	106.9668	7.5843	129.8346	30.4521	0.2269	202	876.64	722.08	762.31	23214	5.30	185.1	106839720	0.022	90.834	10.56	
C8430	72hr	4	97	3603	106.4402	9.0799	132.4731	35.1128	0.1959	2066	10495.15	10338.59	10411.95	365583	69.76	187.6	108282720	0.338	89.616	1.41	
C8430	72hr	4	97	3603	106.4402	9.0799	132.4731	35.1128	0.2259	2404	10641.88	10485.31	10411.95	365583	69.76	187.6	108282720	0.338	89.616	1.41	
C8419	96hr	1	97	6305	102.8351	5.2046	118.2762	20.6447	0.2139	33	154.28	NA	NA	NA	NA	0	0	NA	NA	NA	
C8419	96hr	1	97	6305	102.8351	5.2046	118.2762	20.6447	0.2112	31	146.78	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	96hr	1	97	3048	103.3817	6.0769	121.1086	23.8038	0.2130	31	145.54	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	96hr	1	97	3048	103.3817	6.0769	121.1086	23.8038	0.2381	32	134.40	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	96hr	2	96	8801	107.8256	10.7455	136.6235	39.7434	0.2355	25	106.16	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	96hr	2	96	8801	107.8256	10.7455	136.6235	39.7434	0.2205	32	145.12	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	96hr	2	97	0904	105.8811	8.7907	130.9686	33.8792	0.2389	30	125.58	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	96hr	2	97	0904	105.8811	8.7907	130.9686	33.8792	0.2275	27	118.69	NA	NA	NA	NA	0	0	NA	NA	NA	
C8421	96hr	3	97	4332	104.8358	7.5028	127.8520	30.4188	0.1722	77	447.15	301.91	491.07	14938	3.45	149.3	86175960	0.017	86.003	77.04	
C8421	96hr	3	97	4332	104.8358	7.5028	127.8520	30.4188	0.2229	184	825.48	680.23	491.07	14938	3.45	149.3	86175960	0.017	86.003	77.04	
C8422	96hr	3	96	5499	107.8200	8.2701	130.6698	31.1199	0.1977	36	182.09	36.85	22.35	696	0.15	159.5	92063400	0.001	84.874	125.69	
C8422	96hr	3	96	5499	107.8200	8.2701	130.6698	31.1199	0.2286	35	163.11	7.86	22.35	696	0.15	159.5	92063400	0.001	84.874	125.69	
C8423	96hr	3	99	7815	105.5069	5.7254	123.6723	23.8908	0.2213	63	284.89	139.43	140.36	3353	1.01	151.1	87214920	0.004	85.582	1.32	
C8423	96hr	3	99	7815	105.5069	5.7254	123.6723	23.8908	0.2443	70	286.53	141.28	140.36	3353	1.01	151.1	87214920	0.004	85.582	1.32	
C8424	96hr	3	96	2722	105.0625	5.8103	123.0798	23.8076	0.2157	60	278.16	132.92	125.82	2996	0.89	146.3	84444360	0.004	87.987	11.27	
C8424	96hr	3	96	2722	105.0625	5.8103	123.0798	23.8076	0.2235	59	263.96	118.73	125.82	2996	0.89	146.3	84444360	0.004	87.987	11.27	
C8427	96hr	4	97	3878	104.5072	7.1194	127.2570	29.8692	0.2171	119	548.13	424.25	422.75	12927	3.07	186.8	107820960	0.012	88.228	0.71	
C8427	96hr	4	97	3878	104.5072	7.1194	127.2570	29.8692	0.2348	128	545.14	421.26	422.75	12927	3.07	186.8	107820960	0.012	88.228	0.71	
C8428	96hr	4	97	2457	105.8396	8.5929	131.9846	34.7399	0.2000	75	375.00	251.12	250.82	8713	1.78	173.8	100317360	0.009	89.754	0.24	
C8428	96hr	4	97	2457	105.8396	8.5929	131.9846	34.7399	0.2110	79	374.41	250.52	250.82	8713	1.78	173.8	100317360	0.009	89.754	0.24	
C8429	96hr	4	99	0462	107.8509	8.8098	133.8168	34.7706	0.2197	57	259.44	135.56	148.97	5180	1.02	185.1	106839720	0.005	90.839	18	
C8429	96hr	4	99	0462	107.8509	8.8098	133.8168	34.7706	0.2096	60	286.26	162.37	148.97	5180	1.02	185.1	106839720	0.005	90.839	18	
C8430	96hr	4	99	6073	111.2605	11.6532	141.3802	41.7729	0.2375	69	280.53	188.64	164.17	6858	1.02	187.6	108282720	0.006	89.822	3.01	
C8430	96hr	4	99	6073	111.2605	11.6532	141.3802	41.7729	0.2276	65	285.59	181.70	164.17	6858	1.02	187.6	108282720	0.006	89.822	3.01	

Counts in bold letters are repeats. These samples were flagged in the spreadsheets indicating non-uniformity of the sampling.

Control samples from #C8419 and C8420 (72 hr) were replaced with not contaminated control feces.



Dosing solution S.A.= 0.26 µCi/mg= 577200 DPMs/mg

Animal ID	Time Pt.	Group	S ex	Vial Tare		Tare + Sample		Rep. Wt.		Rep. DPM's/g		Conc. DPM's/g		Avg. DPM's/g		Total DPM in sample		Dose (mg)		Dose (DPM)		% Dose		Cum. % dose	
				Female 24hr	Male 24hr	Female 24h	Male 24hr	Female 48hr	Male 48hr	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=	BKG=
BKG= 82	DPM/g	84	DPM/g	81	DPM/g	88	DPM/g	81	DPM/g	87	81	87	81	87	81	87	81	87	81	87	81	87	81	87	81
BKG= 84	DPM/g	84	DPM/g	81	DPM/g	88	DPM/g	81	DPM/g	87	81	87	81	87	81	87	81	87	81	87	81	87	81	87	81
KOH																									
C8419	24hr	1/F		163.4	341.1	177.7	0.4788	37	77	57.66	140	57.66	140	57.66	140	10092	149.3	0	0	86175960	0.012	0.012	0.012	0.012	7.87
C8419	24hr	1/F		163.4	341.1	177.7	0.4788	37	77	57.66	140	57.66	140	57.66	140	10092	149.3	0	0	86175960	0.012	0.012	0.012	0.012	7.87
C8420	24hr	1/F		164.3	336.9	172.6	0.4781	41	86	73.67	156	73.67	156	73.67	156	11745	159.5	0	0	92063400	0.013	0.013	0.013	0.013	4.8
C8420	24hr	1/F		164.3	336.9	172.6	0.4781	41	86	73.67	156	73.67	156	73.67	156	11745	159.5	0	0	92063400	0.013	0.013	0.013	0.013	4.8
C8420	24hr	1/F		165.9	358.8	192.9	0.4786	42	88	77.29	159	77.29	159	77.29	159	12235	151.1	0	0	87214920	0.014	0.014	0.014	0.014	9.26
C8425	24hr	2/M		165.9	358.8	192.9	0.4786	42	88	77.29	159	77.29	159	77.29	159	12235	151.1	0	0	87214920	0.014	0.014	0.014	0.014	9.26
C8425	24hr	2/M		165.9	358.8	192.9	0.4786	42	88	77.29	159	77.29	159	77.29	159	12235	151.1	0	0	87214920	0.014	0.014	0.014	0.014	9.26
C8426	24hr	2/M		166.3	340.0	173.7	0.4853	42	87	72.13	154	72.13	154	72.13	154	10996	146.3	0	0	84444360	0.013	0.013	0.013	0.013	19.5
C8426	24hr	2/M		166.3	340.0	173.7	0.4853	42	87	72.13	154	72.13	154	72.13	154	10996	146.3	0	0	84444360	0.013	0.013	0.013	0.013	19.5
C8421	24hr	3/F		164.6	346.5	181.9	0.4795	67	140	75.48	159	75.48	159	75.48	159	12030	186.8	0	0	107820960	0.011	0.011	0.011	0.011	1.6
C8421	24hr	3/F		164.6	346.5	181.9	0.4795	67	140	75.48	159	75.48	159	75.48	159	12030	186.8	0	0	107820960	0.011	0.011	0.011	0.011	1.6
C8422	24hr	3/F		164.2	319.8	155.6	0.4880	76	132	68.65	152	68.65	152	68.65	152	11358	173.8	0	0	100317360	0.011	0.011	0.011	0.011	1.16
C8422	24hr	3/F		164.2	319.8	155.6	0.4880	76	132	68.65	152	68.65	152	68.65	152	11358	173.8	0	0	100317360	0.011	0.011	0.011	0.011	1.16
C8423	24hr	3/F		164.4	347.3	182.9	0.4799	70	146	75.21	159	75.21	159	75.21	159	12717	185.1	0	0	106839720	0.012	0.012	0.012	0.012	3.8
C8423	24hr	3/F		164.4	347.3	182.9	0.4799	70	146	75.21	159	75.21	159	75.21	159	12717	185.1	0	0	106839720	0.012	0.012	0.012	0.012	3.8
C8424	24hr	3/F		164.5	331.8	167.3	0.4864	75	154	78.59	162	78.59	162	78.59	162	12643	187.6	0	0	108282720	0.012	0.012	0.012	0.012	1.97
C8424	24hr	3/F		164.5	331.8	167.3	0.4864	75	154	78.59	162	78.59	162	78.59	162	12643	187.6	0	0	108282720	0.012	0.012	0.012	0.012	1.97
C8427	24hr	4/M		165.9	324.0	158.1	0.4713	75	132	68.65	152	68.65	152	68.65	152	11358	173.8	0	0	100317360	0.011	0.011	0.011	0.011	1.16
C8427	24hr	4/M		165.9	324.0	158.1	0.4713	75	132	68.65	152	68.65	152	68.65	152	11358	173.8	0	0	100317360	0.011	0.011	0.011	0.011	1.16
C8428	24hr	4/M		165.2	331.6	166.4	0.4793	73	132	68.65	152	68.65	152	68.65	152	11358	173.8	0	0	100317360	0.011	0.011	0.011	0.011	1.16
C8428	24hr	4/M		165.2	331.6	166.4	0.4793	73	132	68.65	152	68.65	152	68.65	152	11358	173.8	0	0	100317360	0.011	0.011	0.011	0.011	1.16
C8429	24hr	4/M		164.6	336.9	172.3	0.4847	77	159	75.21	159	75.21	159	75.21	159	12717	185.1	0	0	106839720	0.012	0.012	0.012	0.012	3.8
C8429	24hr	4/M		164.6	336.9	172.3	0.4847	77	159	75.21	159	75.21	159	75.21	159	12717	185.1	0	0	106839720	0.012	0.012	0.012	0.012	3.8
C8430	24hr	4/M		165.6	324.9	159.3	0.4931	80	162	78.59	162	78.59	162	78.59	162	12643	187.6	0	0	108282720	0.012	0.012	0.012	0.012	1.97
C8430	24hr	4/M		165.6	324.9	159.3	0.4931	80	162	78.59	162	78.59	162	78.59	162	12643	187.6	0	0	108282720	0.012	0.012	0.012	0.012	1.97
C8419	48hr	1/F		164.1	330.2	166.1	0.4796	40	83	75.48	159	75.48	159	75.48	159	12030	186.8	0	0	107820960	0.011	0.011	0.011	0.011	1.6
C8419	48hr	1/F		164.1	330.2	166.1	0.4796	40	83	75.48	159	75.48	159	75.48	159	12030	186.8	0	0	107820960	0.011	0.011	0.011	0.011	1.6
C8420	48hr	1/F		165.6	334.4	168.8	0.4829	38	79	68.65	152	68.65	152	68.65	152	11358	173.8	0	0	100317360	0.011	0.011	0.011	0.011	1.16
C8420	48hr	1/F		165.6	334.4	168.8	0.4829	38	79	68.65	152	68.65	152	68.65	152	11358	173.8	0	0	100317360	0.011	0.011	0.011	0.011	1.16
C8420	48hr	1/F		163.5	333.5	170.0	0.4805	44	92	75.21	159	75.21	159	75.21	159	12717	185.1	0	0	106839720	0.012	0.012	0.012	0.012	3.8
C8425	48hr	2/M		163.5	333.5	170.0	0.4805	44	92	75.21	159	75.21	159	75.21	159	12717	185.1	0	0	106839720	0.012	0.012	0.012	0.012	3.8
C8425	48hr	2/M		164.2	324.5	160.3	0.4748	41	86	73.67	156	73.67	156	73.67	156	11745	159.5	0	0	92063400	0.013	0.013	0.013	0.013	4.8
C8426	48hr	2/M		164.2	324.5	160.3	0.4748	41	86	73.67	156	73.67	156	73.67	156	11745	159.5	0	0	92063400	0.013	0.013	0.013	0.013	4.8
C8426	48hr	2/M		165.8	349.9	184.1	0.4828	43	89	77.29	159	77.29	159	77.29	159	12235	151.1	0	0	87214920	0.014	0.014	0.014	0.014	9.26
C8421	48hr	3/F		165.8	349.9	184.1	0.4828	43	89	77.29	159	77.29	159	77.29	159	12235	151.1	0	0	87214920	0.014	0.014	0.014	0.014	9.26
C8421	48hr	3/F		166	318.7	152.7	0.4878	43	88	75.0	152	75.0	152	75.0	152	1192	159.5	0	0	92063400	0.001	0.001	0.001	0.001	24.9
C8422	48hr	3/F		166	318.7	152.7	0.4878	43	88	75.0	152	75.0	152	75.0	152	1192	159.5	0	0	92063400	0.001	0.001	0.001	0.001	24.9
C8422	48hr	3/F		165.2	342.3	177.1	0.4792	42	88	70.0	151	70.0	151	70.0	151	1102	146.3	0	0	84444360	0.015	0.015	0.015	0.015	19.5
C8423	48hr	3/F		165.2	342.3	177.1	0.4792	42	88	70.0	151	70.0	151	70.0	151	1102	146.3	0	0	84444360	0.015	0.015	0.015	0.015	19.5
C8423	48hr	3/F		165.5	358.6	193.1	0.4797	42	88	6.90	88	6.90	88	6.90	88	1102	146.3	0	0	84444360	0.015	0.015	0.015	0.015	19.5
C8424	48hr	3/F		165.5	358.6	193.1	0.4797	42	88	6.90	88	6.90	88	6.90	88	1102	146.3	0	0	84444360	0.015	0.015	0.015	0.015	19.5

Animal ID	Time Pt.	Group/S	Vial Tare Wt.(g)	Tare + Sample Wt.(g)	KOH Sample Wt.(g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eg/g KOH	Dose (mg)	Dose (DPM)	% Dose	Cum. % dose	% R	F
C8424	48hr	3/F	165.5	368.1	202.6	0.4765	44	92	11.69	9.30	1795	0.016	146.3	84444360	0.002	0.015	51.5	
C8427	48hr	4/M	165.5	368.1	202.6	0.4933	46	93	4.82	2.41	488	0.004	186.8	107820960	0.000	0.012	200	
C8428	48hr	4/M	164.4	353.7	189.3	0.483	42	87	0.00	0.00			186.8	107820960	0.000	0.012	200	
C8428	48hr	4/M	164.4	353.7	189.3	0.4801	41	85	0.00	0.00			173.8	100317360	0.000	0.011	200	
C8428	48hr	4/M	165.5	345.2	179.7	0.4803	43	90	1.10	0.55	104	0.001	173.8	100317360	0.000	0.011	200	
C8429	48hr	4/M	165.5	345.2	179.7	0.4803	44	92	3.18	1.59	285	0.003	185.1	106839720	0.000	0.012	200	
C8429	48hr	4/M	164.1	347.8	183.7	0.4846	41	85	0.00	0.00			185.1	106839720	0.000	0.012	200	
C8430	48hr	4/M	164.1	347.8	183.7	0.4779	44	92	3.64	2.51	460	0.004	187.6	108282720	0.000	0.012	90.2	
C8430	48hr	4/M	165.5	329.4	163.9	0.4788	43	90	1.38	2.51	460	0.004	187.6	108282720	0.000	0.012	90.2	
C8419	72hr	1/F	165.5	329.4	163.9	0.4785	40	84	NA	NA	NA	NA	0	0	NA	NA	NA	
C8419	72hr	1/F	165.5	329.4	163.9	0.4876	42	86	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	72hr	1/F	165.5	332.7	167.2	0.4878	41	84	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	72hr	1/F	165.5	332.7	167.2	0.4816	45	93	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	72hr	2/M	165.4	334.5	169.1	0.4752	42	88	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	72hr	2/M	166.2	331.0	164.8	0.4752	37	78	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	72hr	2/M	166.2	331.0	164.8	0.4787	39	81	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	72hr	2/M	165.9	332.9	167.0	0.4788	36	75	NA	NA	NA	NA	0	0	NA	NA	NA	
C8421	72hr	3/F	165.9	332.9	167.0	0.4818	45	93	6.59	3.30	551	0.006	149.3	86175960	0.001	0.016	200	
C8421	72hr	3/F	166.1	324.0	157.9	0.4794	39	81	0.00	0.00			149.3	86175960	0.001	0.016	200	
C8422	72hr	3/F	166.1	324.0	157.9	0.481	42	87	0.51	0.26	41	0.000	159.5	92063400	0.000	0.014	200	
C8422	72hr	3/F	165.7	329.3	163.6	0.4869	40	82	0.00	0.00			159.5	92063400	0.000	0.014	200	
C8423	72hr	3/F	165.7	329.3	163.6	0.4758	37	78	0.00	0.00			151.1	87214920	0.000	0.015	####	
C8423	72hr	3/F	165.4	337.6	172.2	0.4582	38	83	0.00	0.00	0	0.000	151.1	87214920	0.000	0.015	####	
C8424	72hr	3/F	165.4	337.6	172.2	0.4763	41	86	0.00	0.00			146.3	84444360	0.000	0.015	####	
C8424	72hr	3/F	165.8	335.0	169.2	0.4751	40	84	0.00	0.00	0	0.000	146.3	84444360	0.000	0.015	####	
C8427	72hr	4/M	166.2	334.8	168.6	0.4788	41	86	4.90	8.14	1378	0.014	186.8	107820960	0.001	0.013	79.5	
C8427	72hr	4/M	166.2	334.8	168.6	0.4777	44	92	11.38	8.14	1378	0.014	186.8	107820960	0.001	0.013	79.5	
C8428	72hr	4/M	166.1	330.3	164.2	0.4764	41	86	5.34	6.65	1121	0.012	173.8	100317360	0.001	0.013	39.5	
C8428	72hr	4/M	166.1	330.3	164.2	0.4961	44	89	7.97	6.65	1121	0.012	173.8	100317360	0.001	0.013	39.5	
C8429	72hr	4/M	165.3	332.9	167.6	0.4795	43	90	8.95	8.05	1321	0.014	185.1	106839720	0.001	0.013	22.5	
C8429	72hr	4/M	165.3	332.9	167.6	0.4780	42	88	7.14	8.05	1321	0.014	185.1	106839720	0.001	0.013	22.5	
C8430	72hr	4/M	166	344.7	178.7	0.4840	40	83	1.92	3.28	549	0.006	187.6	108282720	0.001	0.013	82.9	
C8430	72hr	4/M	166	344.7	178.7	0.4803	41	85	4.84	3.28	549	0.006	187.6	108282720	0.001	0.013	82.9	
C8419	96hr	1/F	166	344.7	178.7	0.4740	41	86	NA	NA	NA	NA	0	0	NA	NA	NA	
C8419	96hr	1/F	165.9	345.6	179.7	0.4774	38	80	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	96hr	1/F	165.9	345.6	179.7	0.4767	37	78	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	96hr	1/F	165.9	345.6	179.7	0.4778	40	84	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	96hr	2/M	165.9	332.9	167.0	0.4744	38	80	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	96hr	2/M	165.6	350.0	184.4	0.4889	42	86	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	96hr	2/M	165.6	350.0	184.4	0.4770	37	78	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	96hr	2/M	165.9	340.2	174.3	0.4767	40	84	NA	NA	NA	NA	0	0	NA	NA	NA	
C8421	96hr	3/F	165.9	340.2	174.3	0.4763	42	88	6.32	3.16	551	0.005	149.3	86175960	0.001	0.016	200	
C8421	96hr	3/F	166.1	334.6	168.5	0.4776	39	82	0.00	3.16	551	0.005	149.3	86175960	0.001	0.016	200	
C8422	96hr	3/F	166.1	334.6	168.5	0.4801	41	85	3.54	18.09	3047	0.031	159.5	92063400	0.003	0.017	161	
C8422	96hr	3/F	166.1	334.6	168.5	0.4804	55	114	32.63	18.09	3047	0.031	159.5	92063400	0.003	0.017	161	

Animal ID	Time Pt.	Group/S ex	Vial Tare Wt.(g)	Tare + Sample Wt.(g)	KOH Sample Wt.(g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eg/g KOH	Dose (mg)	Dose (DPM)	% Dose	Cum. % dose	% R	F
C8423	96hr	3/F	165.2	356.0	190.8	0.4756	40	84	2.25	1.22	233	0.002	151.1	87214920	0.000	0.016	168	
C8423	96hr	3/F				0.4753	39	82	0.20				151.1	87214920	0.000	0.016	168	
C8424	96hr	3/F	165.7	351.2	185.5	0.4767	42	88	6.25				146.3	84444360				
C8424	96hr	3/F				0.4759	44	92	10.60	8.42	1563	0.015	146.3	84444360	0.002	0.017	51.7	
C8427	96hr	4/M	165.2	347.7	182.5	0.4672	40	86	3.74				186.8	107820960				
C8427	96hr	4/M				0.4736	41	87	4.70	4.22	771	0.007	186.8	107820960	0.001	0.014	22.6	
C8428	96hr	4/M	166.5	348.1	181.6	0.4743	39	82	0.35				173.8	100317360				
C8428	96hr	4/M				0.4741	41	86	4.61	2.48	451	0.004	173.8	100317360	0.000	0.013	171	
C8429	96hr	4/M	165.4	349.6	184.2	0.4757	43	90	8.52				185.1	106839720				
C8429	96hr	4/M				0.4672	41	88	5.89	7.20	1327	0.012	185.1	106839720	0.001	0.015	36.6	
C8430	96hr	4/M	165.5	350.1	184.6	0.4798	36	75	0.00				187.6	108282720				
C8430	96hr	4/M				0.4805	43	89	7.62	3.81	703	0.007	187.6	108282720	0.001	0.013	200	

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Animal ID	Time Pt.	Group	Vial Tare Wt.(g)	Tare + Sample Wt.(g)	Sample Wt. (g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eq/g urine	Dose (mg)	Dose (DPM)	% Dose	Cum. % dose	% RR	F
C8421	24hr	3	97.4716	101.2183	3.7467	0.2650	218	822.64	746.98	742.39	2782	1.286	149.3	86175960	0.003	0.012	1.24	
C8422	24hr	3	97.3753	100.2100	2.8347	0.2645	285	1077.50	1001.84				159.5	92063400				
C8422	24hr	3	97.3753	100.2100	2.8347	0.2654	284	1070.08	994.42	998.13	2829	1.729	159.5	92063400	0.003	0.011	0.74	
C8423	24hr	3	97.4775	100.1435	2.6660	0.2652	289	1089.74	1014.08				151.1	87214920				
C8423	24hr	3	97.4775	100.1435	2.6660	0.2666	283	1061.52	985.85	999.97	2666	1.732	151.1	87214920	0.003	0.007	2.82	
C8424	24hr	3	97.4918	100.9983	3.5065	0.2615	194	741.87	666.21				146.3	84444360				
C8424	24hr	3	97.4918	100.9983	3.5065	0.2633	199	755.79	680.13	673.17	2360	1.166	146.3	84444360	0.003	0.010	2.07	
C8427	24hr	4	97.3448	102.2716	4.9268	0.2615	237	906.31	829.09				186.8	107820960				
C8427	24hr	4	97.3448	102.2716	4.9268	0.2604	253	971.58	894.36	861.73	4246	1.493	186.8	107820960	0.004	0.012	7.57	
C8428	24hr	4	97.5372	102.7769	5.2397	0.2614	248	948.74	871.52				173.8	100317360				
C8428	24hr	4	97.5372	102.7769	5.2397	0.2639	252	954.91	877.69	874.60	4583	1.515	173.8	100317360	0.005	0.014	0.71	
C8429	24hr	4	97.2856	102.4955	5.2099	0.2623	229	873.05	795.83				185.1	106839720				
C8429	24hr	4	97.2856	102.4955	5.2099	0.2637	229	868.41	791.19	793.51	4134	1.375	185.1	106839720	0.004	0.013	0.58	
C8430	24hr	4	97.0444	103.3375	6.2931	0.2628	209	795.28	718.06				187.6	108282720				
C8430	24hr	4	97.0444	103.3375	6.2931	0.2600	200	769.23	692.01	705.04	4437	1.221	187.6	108282720	0.004	0.013	3.69	
C8419	48hr	1	97.1157	106.3360	9.2203	0.2626	19	72.35					0	0				
C8419	48hr	1	97.1157	106.3360	9.2203	0.2593	20	77.13	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	48hr	1	97.2094	104.4724	7.2630	0.2662	18	67.62					0	0				
C8420	48hr	1	97.2094	104.4724	7.2630	0.2607	19	72.88	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	48hr	2	96.9815	99.1079	2.1284	0.2587	21	81.18					0	0				
C8425	48hr	2	96.9815	99.1079	2.1284	0.2538	19	74.86	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	48hr	2	97.3039	107.2951	9.9912	0.2527	20	79.15					0	0				
C8426	48hr	2	97.3039	107.2951	9.9912	0.2579	17	65.92	NA	NA	NA	NA	0	0	NA	NA	NA	
C8421	48hr	3	98.8621	105.7803	6.9182	0.2648	67	253.02	180.53	174.97	1210	0.303	149.3	86175960	0.001	0.013	6.35	
C8422	48hr	3	98.7328	107.3345	8.6017	0.2390	66	276.15	203.65				159.5	92063400				
C8422	48hr	3	98.7328	107.3345	8.6017	0.2561	70	273.33	200.83	202.24	1740	0.350	159.5	92063400	0.002	0.012	1.39	
C8423	48hr	3	98.1191	102.2999	4.1808	0.2652	93	350.68	278.18				151.1	87214920				
C8423	48hr	3	98.1191	102.2999	4.1808	0.2568	89	346.57	274.08	276.13	1154	0.478	151.1	87214920	0.001	0.008	1.49	
C8424	48hr	3	98.8026	107.7391	8.9365	0.2392	55	229.93	157.44				146.3	84444360				
C8424	48hr	3	98.8026	107.7391	8.9365	0.2549	55	215.77	143.28	150.36	1344	0.260	146.3	84444360	0.002	0.011	9.42	
C8427	48hr	4	98.4279	106.4666	8.0387	0.2587	85	328.57	253.29				186.8	107820960				
C8427	48hr	4	98.4279	106.4666	8.0387	0.2584	94	363.78	288.50	270.90	2178	0.469	186.8	107820960	0.002	0.015	13	
C8428	48hr	4	98.5139	109.8612	11.3473	0.2646	52	196.52	121.25				173.8	100317360				
C8428	48hr	4	98.5139	109.8612	11.3473	0.2611	53	202.99	127.71	124.48	1413	0.216	173.8	100317360	0.001	0.015	5.19	
C8429	48hr	4	98.7362	105.0263	6.2901	0.2594	88	339.24	263.97				185.1	106839720				
C8429	48hr	4	98.7362	105.0263	6.2901	0.2638	76	288.10	212.82	238.40	1500	0.413	185.1	106839720	0.001	0.014	21.45	
C8430	48hr	4	98.6386	109.7408	11.1022	0.2570	73	284.05	208.77				187.6	108282720				
C8430	48hr	4	98.6386	109.7408	11.1022	0.2597	60	231.04	155.76	182.27	2024	0.316	187.6	108282720	0.002	0.015	29.08	
C8419	72hr	1	98.8645	106.9207	8.0562	0.2597	19	73.16					0	0				
C8419	72hr	1	98.8645	106.9207	8.0562	0.2608	18	69.02	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	72hr	1	98.4176	107.2124	8.7948	0.2569	16	62.28					0	0				
C8420	72hr	1	98.4176	107.2124	8.7948	0.2578	20	77.58	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	72hr	2	98.6327	99.5146	0.8819	0.2691	20	74.32					0	0				
C8425	72hr	2	98.6327	99.5146	0.8819	0.2668	19	71.21	NA	NA	NA	NA	0	0	NA	NA	NA	

Animal ID	Time	Plt	Group	Vial	Tare + Sample Wt. (g)	Sample Wt. (g)	Rep. Wt. (g)	Rep.	Conc. DPM's/g	DPMS/g corrected	Avg. DPM's/g sample	Total DPM in sample	Conc. ug Eg/g urine	Dose (mg)	Dose (DPM)	% Dose	Cum. % dose	% RR	F
C8426	72hr	2	2	98.7234	108.1674	9.4440	0.2639	21	79.58	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	72hr	2	2	98.7234	108.1674	9.4440	0.2630	20	76.05	NA	NA	NA	NA	0	0	NA	NA	NA	
C8421	72hr	3	3	98.5881	106.4377	7.8496	0.2633	36	136.73	66.22	63.04	495	0.109	149.3	86175960	0.001	0.014	10.09	
C8421	72hr	3	3	98.5881	106.4377	7.8496	0.2608	34	130.37	59.86	63.04	495	0.109	149.3	86175960	0.001	0.014	10.09	
C8422	72hr	3	3	98.3768	106.3208	7.9440	0.2587	51	197.14	126.63	113.60	902	0.197	159.5	92063400	0.001	0.013	22.95	
C8422	72hr	3	3	98.3768	106.3208	7.9440	0.2572	44	171.07	100.56	113.60	902	0.197	159.5	92063400	0.001	0.013	22.95	
C8423	72hr	3	3	98.8457	105.4578	6.6121	0.2629	34	129.33	58.82	60.57	400	0.105	151.1	87214920	0.000	0.009	5.78	
C8423	72hr	3	3	98.8457	105.4578	6.6121	0.2635	35	132.83	62.32	60.57	400	0.105	151.1	87214920	0.000	0.009	5.78	
C8424	72hr	3	3	98.4310	106.9285	8.4975	0.2559	36	140.68	70.17	73.08	621	0.127	146.3	84444360	0.001	0.012	7.95	
C8424	72hr	3	3	98.4310	106.9285	8.4975	0.2594	38	146.49	75.98	73.08	621	0.127	146.3	84444360	0.001	0.012	7.95	
C8427	72hr	4	4	98.4230	107.8780	9.4550	0.2580	49	189.92	114.63	112.41	1063	0.195	186.8	107820960	0.001	0.016	3.96	
C8427	72hr	4	4	98.4230	107.8780	9.4550	0.2588	48	185.47	110.18	112.41	1063	0.195	186.8	107820960	0.001	0.016	3.96	
C8428	72hr	4	4	98.6841	109.1718	10.4877	0.2593	35	134.98	59.69	51.34	538	0.089	173.8	100317360	0.001	0.015	32.54	
C8428	72hr	4	4	98.6841	109.1718	10.4877	0.2621	31	118.28	42.99	51.34	538	0.089	173.8	100317360	0.001	0.015	32.54	
C8429	72hr	4	4	98.7073	106.1549	7.4476	0.2558	42	164.19	88.90	84.93	633	0.147	185.1	106839720	0.001	0.015	9.35	
C8429	72hr	4	4	98.7073	106.1549	7.4476	0.2624	41	156.25	80.96	84.93	633	0.147	185.1	106839720	0.001	0.015	9.35	
C8430	72hr	4	4	99.0544	109.9346	10.8802	0.2601	27	103.81	28.52	28.44	309	0.049	187.6	108282720	0.000	0.015	0.56	
C8430	72hr	4	4	99.0544	109.9346	10.8802	0.2605	27	103.65	28.36	28.44	309	0.049	187.6	108282720	0.000	0.015	0.56	
C8419	96hr	1	1	98.1986	105.9071	7.7085	0.2586	18	69.61	NA	NA	NA	NA	0	0	NA	NA	NA	
C8419	96hr	1	1	98.1986	105.9071	7.7085	0.2561	20	78.09	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	96hr	1	1	98.7592	112.5206	13.7614	0.2579	19	73.67	NA	NA	NA	NA	0	0	NA	NA	NA	
C8420	96hr	1	1	98.7592	112.5206	13.7614	0.2470	17	68.83	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	96hr	2	2	98.7682	102.2718	3.5036	0.2648	19	71.75	NA	NA	NA	NA	0	0	NA	NA	NA	
C8425	96hr	2	2	98.7682	102.2718	3.5036	0.2642	21	79.49	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	96hr	2	2	98.4206	108.9824	10.5618	0.2641	19	71.94	NA	NA	NA	NA	0	0	NA	NA	NA	
C8426	96hr	2	2	98.4206	108.9824	10.5618	0.2499	20	80.03	NA	NA	NA	NA	0	0	NA	NA	NA	
C8421	96hr	3	3	100.1567	106.6616	6.5049	0.2611	29	111.07	38.52	46.06	300	0.080	149.3	86175960	0.000	0.014	32.74	
C8421	96hr	3	3	100.1567	106.6616	6.5049	0.2616	33	126.15	53.60	46.06	300	0.080	149.3	86175960	0.000	0.014	32.74	
C8422	96hr	3	3	100.0506	109.8339	9.7833	0.2566	34	132.50	59.95	67.52	661	0.117	159.5	92063400	0.001	0.014	22.41	
C8422	96hr	3	3	100.0506	109.8339	9.7833	0.2574	38	147.63	75.08	67.52	661	0.117	159.5	92063400	0.001	0.014	22.41	
C8423	96hr	3	3	99.9192	105.6559	5.7367	0.2648	31	117.07	44.52	46.50	267	0.081	151.1	87214920	0.000	0.009	8.51	
C8423	96hr	3	3	99.9192	105.6559	5.7367	0.2644	32	121.03	48.48	46.50	267	0.081	151.1	87214920	0.000	0.009	8.51	
C8424	96hr	3	3	99.4386	108.3418	8.9032	0.2594	47	181.19	108.64	104.83	933	0.192	146.3	84444360	0.001	0.013	7.27	
C8424	96hr	3	3	99.4386	108.3418	8.9032	0.2535	44	173.57	101.02	104.83	933	0.192	146.3	84444360	0.001	0.013	7.27	
C8427	96hr	4	4	99.9513	109.2293	9.2780	0.2588	41	158.42	82.62	79.23	735	0.137	186.8	107820960	0.001	0.016	8.57	
C8427	96hr	4	4	99.9513	109.2293	9.2780	0.2506	38	151.64	75.83	79.23	735	0.137	186.8	107820960	0.001	0.016	8.57	
C8428	96hr	4	4	100.0005	108.8376	8.8371	0.2606	30	115.12	39.32	41.26	365	0.071	173.8	100317360	0.000	0.016	9.41	
C8428	96hr	4	4	100.0005	108.8376	8.8371	0.2605	31	119.00	43.20	41.26	365	0.071	173.8	100317360	0.000	0.016	9.41	
C8429	96hr	4	4	99.3082	106.2324	6.9242	0.2640	39	147.73	71.92	78.21	542	0.136	185.1	106839720	0.001	0.015	16.08	
C8429	96hr	4	4	99.3082	106.2324	6.9242	0.2620	42	160.31	84.50	78.21	542	0.136	185.1	106839720	0.001	0.015	16.08	
C8430	96hr	4	4	100.4042	111.0180	10.6138	0.2611	25	95.75	19.95	16.58	176	0.029	187.6	108282720	0.000	0.015	40.66	
C8430	96hr	4	4	100.4042	111.0180	10.6138	0.2594	23	89.01	13.21	16.58	176	0.029	187.6	108282720	0.000	0.015	40.66	

Dosing solution S.A 0.26 µCi/mg= 577200 DPMs/mg

BKG= 152 DPM/g Female 96hr

BKG= 158 DPM/g Male 96hr

## GI Tract Content

Animal ID	Time Pt.	Group	Tare Wt. (g)	Sample + Rinse water Wt. (g)	Sample + Rinse Wt. (g)	Sample (GI content) Wt. (g)	Tare + Rinse + RO water Wt. (g)	Homogen. Wt. (g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in homog. content	Conc. ug Eq/g GI	Dose (mg)	Dose (DPM) % Dose	% RR	F
C8419	96hr	1	99.9942	108.5876	8.5934	8.5934	133.8976	33.9034	0.1787	28	156.69	NA	NA	NA	NA	0	0	NA	NA
C8419	96hr	1	99.9942	108.5876	8.5934	8.5934	128.8679	28.2941	0.1998	31	155.16	NA	NA	NA	NA	0	0	NA	NA
C8420	96hr	1	100.5738	109.2259	8.6521	8.6521	128.8679	28.2941	0.2102	36	180.78	NA	NA	NA	NA	0	0	NA	NA
C8420	96hr	1	100.5738	109.2259	8.6521	8.6521	128.8679	28.2941	0.2265	26	114.79	NA	NA	NA	NA	0	0	NA	NA
C8425	96hr	2	100.0046	113.7468	13.7422	10.7422	144.571	44.5664	0.2015	29	143.92	NA	NA	NA	NA	0	0	NA	NA
C8425	96hr	2	100.0046	113.7468	13.7422	10.7422	144.571	44.5664	0.2161	25	115.69	NA	NA	NA	NA	0	0	NA	NA
C8426	96hr	2	99.4810	115.2050	15.7240	12.7240	151.8964	52.4154	0.2125	39	183.53	NA	NA	NA	NA	0	0	NA	NA
C8426	96hr	2	99.4810	115.2050	15.7240	12.7240	151.8964	52.4154	0.1954	37	189.36	NA	NA	NA	NA	0	0	NA	NA
C8421	96hr	3	99.5351	106.3786	6.8435	6.8435	126.3383	26.8032	0.1985	34	171.28	19.43	12.86	345	0.087	149.3	86175960	0.000	102.17
C8421	96hr	3	99.5351	106.3786	6.8435	6.8435	126.3383	26.8032	0.1897	30	158.14	6.29	12.86	345	0.087	149.3	86175960	0.000	102.17
C8422	96hr	3	99.9213	108.8426	8.9213	6.9213	128.9635	29.0422	0.1905	35	183.73	31.87	15.94	463	0.116	159.5	92063400	0.001	200
C8422	96hr	3	99.9213	108.8426	8.9213	6.9213	128.9635	29.0422	0.1964	29	147.66	0.00	15.94	463	0.116	159.5	92063400	0.001	200
C8423	96hr	3	99.6315	111.2704	11.6389	8.6389	136.5513	36.9198	0.2046	32	156.40	4.55	21.77	804	0.161	151.1	87214920	0.001	158.2
C8423	96hr	3	99.6315	111.2704	11.6389	8.6389	136.5513	36.9198	0.2096	40	190.84	38.99	21.77	804	0.161	151.1	87214920	0.001	158.2
C8424	96hr	3	99.6226	110.5586	10.9360	7.9360	133.3229	33.7003	0.2082	35	168.11	16.25	8.13	274	0.060	146.3	84444360	0.000	200
C8424	96hr	3	99.6226	110.5586	10.9360	7.9360	133.3229	33.7003	0.2122	31	146.09	0.00	8.13	274	0.060	146.3	84444360	0.000	200
C8427	96hr	4	99.6144	113.654	14.0396	12.0396	148.5117	48.8973	0.2162	40	185.01	26.89	38.60	1888	0.272	186.8	107820960	0.002	60.68
C8427	96hr	4	99.6144	113.654	14.0396	12.0396	148.5117	48.8973	0.2015	42	208.44	50.31	38.60	1888	0.272	186.8	107820960	0.002	60.68
C8428	96hr	4	100.0933	113.1428	13.0495	10.0495	142.3673	42.2740	0.1772	29	163.66	5.53	2.77	117	0.020	173.8	100317360	0.000	200
C8428	96hr	4	100.0933	113.1428	13.0495	10.0495	142.3673	42.2740	0.1765	27	152.97	0.00	2.77	117	0.020	173.8	100317360	0.000	200
C8429	96hr	4	99.1760	109.87	10.6940	7.6940	132.6275	33.4515	0.2062	35	169.74	11.62	10.35	346	0.078	185.1	106839720	0.000	24.44
C8429	96hr	4	99.1760	109.87	10.6940	7.6940	132.6275	33.4515	0.2153	36	167.21	9.09	10.35	346	0.078	185.1	106839720	0.000	24.44
C8430	96hr	4	99.3203	114.2643	14.9440	11.9440	148.5281	49.2078	0.2085	28	134.29	0.00	0.00	0	0.000	187.6	108282720	0.000	#DIV/0!
C8430	96hr	4	99.3203	114.2643	14.9440	11.9440	148.5281	49.2078	0.2216	28	126.35	0.00	0.00	0	0.000	187.6	108282720	0.000	#DIV/0!



Dosing solution S 0.26 µCi/mg= 577200 DPMs/mg  
 BKG= 41 DPM/g Female 96hr  
 BKG= 45 DPM/g Male 96hr  
 GI Tract emptied)

Animal ID	Time Pt.	Group	Tare		Tare + Sample		Homog.	Rep. Wt.	Rep.	Conc.	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eq/g GI tract	Dose (mg)	Dose (DPM)	% Dose	% RR	F
			Wt.(g)	Wt.(g)	Wt.(g)	Wt.(g)	Wt.(g)	(g)	DPM's	DPM's/g	DPM's/g	DPM's/g	DPM	DPM	DPM	DPM	DPM	DPM	DPM
C8419	96hr	1	98.6110	107.5912	114.0424	6.4512	14.4314	0.5130	24	46.78	NA	NA	NA	NA	0	0	NA	NA	NA
C8419	96hr	1	99.6110	107.5912	114.0424	6.4512	14.4314	0.5061	19	37.54	NA	NA	NA	NA	0	0	NA	NA	NA
C8420	96hr	1	98.9075	106.8813	114.0507	7.1694	15.1432	0.5122	20	39.05	NA	NA	NA	NA	0	0	NA	NA	NA
C8420	96hr	1	98.9075	106.8813	114.0507	7.1694	15.1432	0.4939	21	42.52	NA	NA	NA	NA	0	0	NA	NA	NA
C8425	96hr	2	98.4162	109.3642	116.707	7.3428	18.2908	0.5134	23	44.80	NA	NA	NA	NA	0	0	NA	NA	NA
C8425	96hr	2	98.4162	109.3642	116.707	7.3428	18.2908	0.4865	23	46.32	NA	NA	NA	NA	0	0	NA	NA	NA
C8426	96hr	2	100.2587	111.2269	119.7767	8.5498	19.5180	0.5025	22	43.78	NA	NA	NA	NA	0	0	NA	NA	NA
C8426	96hr	2	100.2587	111.2269	119.7767	8.5498	19.5180	0.4837	21	43.42	NA	NA	NA	NA	0	0	NA	NA	NA
C8421	96hr	3	98.359	106.3484	112.408	6.0596	14.0490	0.4932	36	72.99	31.52	29.23	411	0.117	149.3	86175960	0.000	15.68	
C8421	96hr	3	98.359	106.3484	112.408	6.0596	14.0490	0.4970	34	68.41	26.94	29.23	411	0.117	149.3	86175960	0.000	15.68	
C8422	96hr	3	99.5419	107.5556	114.6673	7.1117	15.1254	0.4962	37	74.57	33.09	24.81	375	0.091	159.5	92063400	0.000	66.77	
C8422	96hr	3	99.5419	107.5556	114.6673	7.1117	15.1254	0.5000	29	58.00	16.53	24.81	375	0.091	159.5	92063400	0.000	66.77	
C8423	96hr	3	98.5409	106.5028	113.0003	6.4975	14.4594	0.4976	34	68.33	26.86	28.73	415	0.111	151.1	87214920	0.000	13.05	
C8423	96hr	3	98.5409	106.5028	113.0003	6.4975	14.4594	0.4856	35	72.08	30.60	28.73	415	0.111	151.1	87214920	0.000	13.05	
C8424	96hr	3	99.728	107.7215	113.7692	6.0477	14.0412	0.4993	35	70.10	28.63	28.33	398	0.114	146.3	84444360	0.000	2.11	
C8424	96hr	3	99.728	107.7215	113.7692	6.0477	14.0412	0.4892	34	69.50	28.03	28.33	398	0.114	146.3	84444360	0.000	2.11	
C8427	96hr	4	98.9913	109.9287	117.5070	7.5783	18.5157	0.4817	36	74.74	30.16	31.56	584	0.134	186.8	107820960	0.001	8.87	
C8427	96hr	4	98.9913	109.9287	117.5070	7.5783	18.5157	0.5030	39	77.53	32.95	31.56	584	0.134	186.8	107820960	0.001	8.87	
C8428	96hr	4	98.1839	109.1751	117.0741	7.8990	18.8902	0.4981	33	66.25	21.67	19.71	372	0.082	173.8	100317360	0.000	19.86	
C8428	96hr	4	98.1839	109.1751	117.0741	7.8990	18.8902	0.4973	31	62.34	17.76	19.71	372	0.082	173.8	100317360	0.000	19.86	
C8429	96hr	4	98.324	109.2962	117.4611	8.1649	19.1371	0.4991	34	68.12	23.54	25.87	495	0.105	185.1	106839720	0.000	17.97	
C8429	96hr	4	98.324	109.2962	117.4611	8.1649	19.1371	0.4947	36	72.77	28.19	25.87	495	0.105	185.1	106839720	0.000	17.97	
C8430	96hr	4	98.6629	109.6657	118.0602	8.3945	19.3973	0.4948	33	66.69	22.11	22.91	444	0.092	187.6	108282720	0.000	6.99	
C8430	96hr	4	98.6629	109.6657	118.0602	8.3945	19.3973	0.4832	33	68.29	23.71	22.91	444	0.092	187.6	108282720	0.000	6.99	

Dosing solution S. 0.26 µCi/mg= 577200 DPMs/mg

BKG= 78.89 DPM/g Female 96hr

BKG= 75.73 DPM/g Male 96hr

Fat

Animal ID	Time Pt	Group	Tare Wt.(g)	Tare + Sample		Homog. Wt. (g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eq/g fat	Dose (mg)	Dose (DPM)	% Dose	% RR	F
				TEAH Wt. (g)	TEAH + Sample Wt. (g)													
C8419	96hr	1	17.2054	18.8089	19.0153	0.2064	0.2413	18	74.60	NA	NA	NA	NA	0	0	NA	NA	NA
C8419	96hr	1	17.2054	18.8089	19.0153	0.2064	0.2536	21	82.81	NA	NA	NA	NA	0	0	NA	NA	NA
C8420	96hr	1	17.2766	18.8933	19.1878	0.2945	0.2470	18	72.87	NA	NA	NA	NA	0	0	NA	NA	NA
C8420	96hr	1	17.2766	18.8933	19.1878	0.2945	0.2580	22	85.27	NA	NA	NA	NA	0	0	NA	NA	NA
C8425	96hr	2	17.2413	18.8298	19.2006	0.3708	0.2502	20	79.94	NA	NA	NA	NA	0	0	NA	NA	NA
C8425	96hr	2	17.2413	18.8298	19.2006	0.3708	0.2540	19	74.80	NA	NA	NA	NA	0	0	NA	NA	NA
C8426	96hr	2	17.1825	18.7898	18.966	0.1762	0.2385	19	79.66	NA	NA	NA	NA	0	0	NA	NA	NA
C8426	96hr	2	17.1825	18.7898	18.966	0.1762	0.2481	17	68.52	NA	NA	NA	NA	0	0	NA	NA	NA
C8421	96hr	3	17.3032	18.9004	19.0921	0.1917	0.2388	17	71.19	0.00	0.00	0	0.000	149.3	86175960	0.000	#DIV/0!	#DIV/0!
C8421	96hr	3	17.3032	18.9004	19.0921	0.1917	0.2455	17	69.25	0.00	0.00	0	0.000	149.3	86175960	0.000	#DIV/0!	#DIV/0!
C8422	96hr	3	17.2229	18.8319	19.1111	0.2792	0.2472	18	72.82	0.00	0.00	0	0.000	159.5	92063400	0.000	#DIV/0!	#DIV/0!
C8422	96hr	3	17.2229	18.8319	19.1111	0.2792	0.2550	18	70.59	0.00	0.00	0	0.000	159.5	92063400	0.000	#DIV/0!	#DIV/0!
C8423	96hr	3	17.1979	18.8077	18.9945	0.1868	0.2524	18	71.32	0.00	0.00	0	0.000	151.1	87214920	0.000	#DIV/0!	#DIV/0!
C8423	96hr	3	17.1979	18.8077	18.9945	0.1868	0.2578	17	65.94	0.00	0.00	0	0.000	151.1	87214920	0.000	#DIV/0!	#DIV/0!
C8424	96hr	3	17.3627	18.982	19.4685	0.4865	0.2453	18	73.38	0.00	0.00	0	0.000	146.3	84444360	0.000	#DIV/0!	#DIV/0!
C8424	96hr	3	17.3627	18.982	19.4685	0.4865	0.2514	17	67.62	0.00	0.00	0	0.000	146.3	84444360	0.000	#DIV/0!	#DIV/0!
C8427	96hr	4	17.1999	18.8171	19.1374	0.3203	0.2556	18	70.42	0.00	0.00	0	0.000	186.8	107820960	0.000	#DIV/0!	#DIV/0!
C8427	96hr	4	17.1999	18.8171	19.1374	0.3203	0.2551	19	74.48	0.00	0.00	0	0.000	186.8	107820960	0.000	#DIV/0!	#DIV/0!
C8428	96hr	4	17.2674	18.8747	19.2031	0.3284	0.2400	21	87.50	11.77	8.36	16	0.085	173.8	100317360	0.000	81.65	81.65
C8428	96hr	4	17.2674	18.8747	19.2031	0.3284	0.2603	21	80.68	4.95	8.36	16	0.085	173.8	100317360	0.000	81.65	81.65
C8429	96hr	4	17.2713	18.8723	19.0519	0.1796	0.2528	19	75.16	0.00	2.10	4	0.036	185.1	106839720	0.000	200	200
C8429	96hr	4	17.2713	18.8723	19.0519	0.1796	0.2502	20	79.94	4.20	2.10	4	0.036	185.1	106839720	0.000	200	200
C8430	96hr	4	17.2609	18.8689	19.3959	0.5270	0.2458	18	73.23	0.00	0.67	1	0.005	187.6	108282720	0.000	200	200
C8430	96hr	4	17.2609	18.8689	19.3959	0.5270	0.2465	19	77.08	1.35	0.67	1	0.005	187.6	108282720	0.000	200	200

Dosing solution 0.26 µCi/mg= 577200 DPMs/mg

BKG= 63.88 DPM/g Female 96hr

BKG= 65.81 DPM/g Male 96hr

## Spleen

Animal ID	Time Pt	Group	Tare Wt.(g)	Tare + Sample		Homogenate Wt. (g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	Avg. DPM's/g corrected	Total DPM in sample	Conc. ug Eq/g spleen	Dose (mg)	Dose (DPM)	% Dose	% RR	F
				Wt. (g)	Wt. (g)												
C8419	96hr	1	17.2619	18.8477	19.2059	0.3582	1.9440	0.2587	17	65.71	NA	NA	0	0	NA	NA	NA
C8419	96hr	1					0.2594	0.2594	18	69.39	NA	NA	0	0	NA	NA	NA
C8420	96hr	1	17.2081	18.787	19.178	0.3910	1.9699	0.2559	16	62.52	0	0	0	0	NA	NA	NA
C8420	96hr	1					0.2591	0.2591	15	57.89	NA	NA	0	0	NA	NA	NA
C8425	96hr	2	17.4078	19.002	19.4023	0.4003	1.9945	0.2547	16	62.82	0	0	0	0	NA	NA	NA
C8425	96hr	2					0.2607	0.2607	18	69.04	NA	NA	0	0	NA	NA	NA
C8426	96hr	2	17.1067	18.7121	19.1346	0.4225	2.0279	0.2576	18	69.88	0	0	0	0	NA	NA	NA
C8426	96hr	2					0.2602	0.2602	16	61.49	NA	NA	0	0	NA	NA	NA
C8421	96hr	3	17.2491	18.8513	19.1895	0.3382	1.9404	0.2561	21	82.00	18.12	149.3	86175960	86175960	0.000	1.24	1.24
C8421	96hr	3					0.2568	0.2568	21	81.78	17.90	149.3	86175960	86175960	0.000	1.24	1.24
C8422	96hr	3	17.1271	18.7342	19.0704	0.3362	1.9433	0.2584	18	69.66	5.78	159.5	92063400	92063400	0.000	99.82	99.82
C8422	96hr	3					0.2587	0.2587	21	81.18	17.29	151.1	87214920	87214920	0.000	99.82	99.82
C8423	96hr	3	17.2653	18.8534	19.1893	0.3359	1.9240	0.2562	20	78.06	14.18	151.1	87214920	87214920	0.000	43.54	43.54
C8423	96hr	3					0.2603	0.2603	19	72.99	9.11	146.3	84444360	84444360	0.000	43.54	43.54
C8424	96hr	3	17.2288	18.8315	19.2183	0.3868	1.9895	0.2569	16	62.28	0.00	146.3	84444360	84444360	0.000	#DIV/0!	#DIV/0!
C8424	96hr	3					0.2582	0.2582	16	61.97	0.00	146.3	84444360	84444360	0.000	#DIV/0!	#DIV/0!
C8427	96hr	4	17.2488	18.8484	19.2792	0.4308	2.0304	0.2559	20	78.16	12.35	186.8	107820960	107820960	0.000	171.77	171.77
C8427	96hr	4					0.2547	0.2547	17	66.75	0.94	186.8	107820960	107820960	0.000	171.77	171.77
C8428	96hr	4	17.2810	18.8836	19.2620	0.3784	1.9810	0.2530	18	71.15	5.34	173.8	100317360	100317360	0.000	76.07	76.07
C8428	96hr	4					0.2574	0.2574	20	77.70	11.89	173.8	100317360	100317360	0.000	76.07	76.07
C8429	96hr	4	17.1726	18.7705	19.1516	0.3811	1.9790	0.2570	21	81.71	15.90	185.1	106839720	106839720	0.000	192.25	192.25
C8429	96hr	4					0.2571	0.2571	17	66.12	0.31	185.1	106839720	106839720	0.000	192.25	192.25
C8430	96hr	4	17.3254	18.9045	19.3792	0.4747	2.0538	0.2575	19	73.79	7.98	187.6	108282720	108282720	0.000	0.36	0.36
C8430	96hr	4					0.2576	0.2576	19	73.76	7.95	187.6	108282720	108282720	0.000	0.36	0.36

Appendix A  
Kidney

Study # 9345

Dosing solution 0.26 µCi/mg= 577200 DPMs/mg

BKG= 64.95 DPM/g Female 96hr

BKG= 65.23 DPM/g Male 96hr

Kidney

Animal ID	Time Pt.	Group	Tare Wt(g)	Tare + TEAH Wt (g)	Sample Wt (g)	Solubilizer Wt (g)	Homogenate Wt (g)	Rep. Wt (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eq/g kidney	Dose (mg)	Dose (DPM)	% Dose	% RR	F
C8419	96hr	1	17.2728	19.8541	20.9212	1.0671	3.6484	0.2514	18	71.60	NA	NA	NA	NA	0	0	NA	NA	NA
C8419	96hr	1						0.2614	14	53.56	NA	NA	NA	NA	0	0	NA	NA	NA
C8420	96hr	1	17.3857	19.9826	21.1046	1.1220	3.7189	0.2593	17	65.56	NA	NA	NA	NA	0	0	NA	NA	NA
C8420	96hr	1						0.2605	18	69.10	NA	NA	NA	NA	0	0	NA	NA	NA
C8425	96hr	2	17.2655	19.8478	21.2652	1.4174	3.9997	0.2578	15	58.18	NA	NA	NA	NA	0	0	NA	NA	NA
C8425	96hr	2						0.2633	16	60.77	NA	NA	NA	NA	0	0	NA	NA	NA
C8426	96hr	2	17.2296	19.8156	21.1689	1.3533	3.9393	0.2432	18	74.01	NA	NA	NA	NA	0	0	NA	NA	NA
C8426	96hr	2						0.2354	16	67.97	NA	NA	NA	NA	0	0	NA	NA	NA
C8421	96hr	3	17.3207	19.9211	20.9208	0.9997	3.6001	0.2612	22	84.23	19.27	16.24	58	0.101	149.3	86175960	0.000	37.39	37.39
C8421	96hr	3						0.2559	20	78.16	13.20	10.94	39	0.067	159.5	92063400	0.000	38	38
C8422	96hr	3	17.2436	19.8236	20.8416	1.0180	3.5980	0.2574	19	73.82	8.86	17.41	64	0.102	151.1	87214920	0.000	38.76	38.76
C8422	96hr	3						0.2565	20	77.97	13.02	14.16	51	0.078	146.3	84444360	0.000	46.16	46.16
C8423	96hr	3	17.1791	19.7774	20.8746	1.0972	3.6955	0.2566	22	85.74	20.78	10.89	51	0.078	146.3	84444360	0.000	46.16	46.16
C8423	96hr	3						0.2532	20	78.99	14.03	17.41	64	0.102	151.1	87214920	0.000	38.76	38.76
C8424	96hr	3	17.3369	19.8178	20.9535	1.1357	3.6166	0.2505	19	75.85	10.89	14.16	51	0.078	146.3	84444360	0.000	46.16	46.16
C8424	96hr	3						0.2549	21	82.39	17.43	14.16	51	0.078	146.3	84444360	0.000	46.16	46.16
C8427	96hr	4	17.3404	19.9447	21.1931	1.2484	3.8527	0.2573	17	66.07	0.84	10.35	40	0.055	186.8	107820960	0.000	183.83	183.83
C8427	96hr	4						0.2585	22	85.11	19.87	10.35	40	0.055	186.8	107820960	0.000	183.83	183.83
C8428	96hr	4	17.1388	19.7453	21.2118	1.4665	4.0730	0.2573	19	73.84	8.61	12.31	50	0.059	173.8	100317360	0.000	60.08	60.08
C8428	96hr	4						0.2585	21	81.24	16.00	12.31	50	0.059	173.8	100317360	0.000	60.08	60.08
C8429	96hr	4	17.2039	19.7854	20.8777	1.0923	3.6738	0.2585	20	77.37	12.14	13.23	49	0.077	185.1	106839720	0.000	16.52	16.52
C8429	96hr	4						0.2514	20	79.55	14.32	13.23	49	0.077	185.1	106839720	0.000	16.52	16.52
C8430	96hr	4	17.3401	19.9302	21.5709	1.6407	4.2308	0.2493	20	80.22	14.99	16.14	68	0.072	187.6	108282720	0.000	14.19	14.19
C8430	96hr	4						0.2545	21	82.51	17.28	16.14	68	0.072	187.6	108282720	0.000	14.19	14.19

★

Dosing solution S.A. 0.26 µCi/mg= 577200 DPMs/mg

BKG= 62.45 DPM/g Female 96hr

BKG= 58.31 DPM/g Male 96hr

Liver

Animal ID	Time Pt.	Group	Tare		Tare + Sample		Homog.	Rep. Wt.	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Ed/g liver	Dose (mg)	Dose (DPM)	% Dose	% RR	F
			Wt. (g)	TEAH Wt. (g)	Wt. (g)	TEAH Wt. Solubilizer (liver) Wt. (g)	Wt. (g)	(g)	(g)	DPM's/g	DPM's/g	DPM's/g	DPM in sample	Ed/g liver	(mg)				
C8419	96hr	1	98.9404	106.9921	112.0107	5.0186	13.0703	0.2549	18	70.62	NA	NA	NA	NA	0	0	NA	NA	
C8419	96hr	1						0.2604	19	72.96	NA	NA	NA	NA	0	0	NA	NA	
C8420	96hr	1	96.8273	104.8923	110.4505	5.5582	13.6232	0.2650	14	52.83	NA	NA	NA	NA	0	0	NA	NA	
C8420	96hr	1						0.2623	14	53.37	NA	NA	NA	NA	0	0	NA	NA	
C8425	96hr	2	99.0601	109.7627	117.7434	7.9807	18.6833	0.2619	14	53.46	NA	NA	NA	NA	0	0	NA	NA	
C8425	96hr	2						0.2557	13	50.84	NA	NA	NA	NA	0	0	NA	NA	
C8426	96hr	2	98.7845	109.923	118.6745	8.7515	19.8900	0.2599	18	69.26	NA	NA	NA	NA	0	0	NA	NA	
C8426	96hr	2						0.2681	16	59.88	NA	NA	NA	NA	0	0	NA	NA	
C8421	96hr	3	98.2197	106.3079	110.0025	3.6946	11.7828	0.2569	22	85.64	23.19	25.59	302	0.141	149.3	86175960	0.000	18.79	
C8421	96hr	3						0.2543	23	90.44	28.00	25.59	302	0.141	149.3	86175960	0.000	18.79	
C8422	96hr	3	99.4177	107.5114	112.6494	5.1380	13.2317	0.2521	24	95.20	32.75	28.58	378	0.128	159.5	92063400	0.000	29.2	
C8422	96hr	3						0.2533	22	86.85	24.41	28.58	378	0.128	159.5	92063400	0.000	29.2	
C8423	96hr	3	99.3584	107.4784	112.7558	5.2774	13.3974	0.257	23	89.49	27.05	21.44	287	0.094	151.1	87214920	0.000	52.32	
C8423	96hr	3						0.2555	20	78.28	15.83	21.44	287	0.094	151.1	87214920	0.000	52.32	
C8424	96hr	3	98.8865	107.0047	112.9150	5.9103	14.0285	0.2524	26	103.01	40.56	27.08	380	0.111	146.3	84444360	0.000	99.57	
C8424	96hr	3						0.2630	20	76.05	13.60	27.08	380	0.111	146.3	84444360	0.000	99.57	
C8427	96hr	4	98.8261	109.9512	118.076	8.1248	19.2499	0.2602	21	80.71	22.40	21.71	418	0.089	186.8	107820960	0.000	6.32	
C8427	96hr	4						0.2647	21	79.34	21.03	21.71	418	0.089	186.8	107820960	0.000	6.32	
C8428	96hr	4	99.7391	111.0547	119.8474	8.7927	20.1083	0.2640	27	102.27	43.96	37.02	745	0.147	173.8	100317360	0.001	37.49	
C8428	96hr	4						0.2602	23	88.39	30.09	37.02	745	0.147	173.8	100317360	0.001	37.49	
C8429	96hr	4	99.4994	110.8508	118.8040	7.9532	19.3046	0.2584	21	81.27	22.96	23.68	457	0.100	185.1	106839720	0.000	6.08	
C8429	96hr	4						0.2539	21	82.71	24.40	23.68	457	0.100	185.1	106839720	0.000	6.08	
C8430	96hr	4	98.6141	110.2392	119.8018	9.5626	21.1877	0.2603	18	69.15	10.84	20.06	425	0.077	187.6	108282720	0.000	91.9	
C8430	96hr	4						0.2626	23	87.59	29.28	20.06	425	0.077	187.6	108282720	0.000	91.9	

Dosing sol'n S.A. 0.26 µCi/mg= 577200 DPM/mg

BKG= 72.75 DPM/g Female 96hr

BKG= 74.15 DPM/g Male 96hr

Eye

Animal ID	Time Pt	Group	Tare Wt.(g)	Tare +		Homog. Wt.(g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eq/g eyes	Dose (mg)	Dose (DPM)	% Dose	% RR	F
				Tare Wt.(g)	Sample + TEAH Wt. (g)													
C8419	96hr	1	17.2097	19.2498	19.4772	0.2274	0.2508	19	75.76	NA	NA	NA	NA	0	0	0	NA	NA
C8419	96hr	1	17.2097	19.2498			0.2568	20	77.88	NA	NA	NA	NA	0	0	0	NA	NA
C8420	96hr	1	17.1873	18.7937	19.0342	0.2405	0.2527	18	71.23	NA	NA	NA	NA	0	0	0	NA	NA
C8420	96hr	1	17.1873	18.7937			0.2570	17	66.15	NA	NA	NA	NA	0	0	0	NA	NA
C8425	96hr	2	17.3094	18.8969	19.0273	0.1304	0.2546	19	74.63	NA	NA	NA	NA	0	0	0	NA	NA
C8425	96hr	2	17.3094	18.8969			0.2587	19	73.44	NA	NA	NA	NA	0	0	0	NA	NA
C8426	96hr	2	17.2918	18.8836	19.0691	0.1855	0.2528	20	79.11	NA	NA	NA	NA	0	0	0	NA	NA
C8426	96hr	2	17.2918	18.8836			0.2593	18	69.42	NA	NA	NA	NA	0	0	0	NA	NA
C8421	96hr	3	17.2384	18.8403	19.0730	0.2327	0.2555	16	62.62	0.00	0.37	1	0.005	149.3	86175960	0.000	200	200
C8421	96hr	3	17.2384	18.8403			0.2585	19	73.50	0.75	1.49	3	0.022	149.3	86175960	0.000	200	200
C8422	96hr	3	17.2352	18.8325	19.0739	0.2414	0.2541	19	74.77	2.02	3.64	7	0.052	159.5	92063400	0.000	200	200
C8422	96hr	3	17.2352	18.8325			0.2580	17	65.89	0.00	1.01	2	0.013	159.5	92063400	0.000	200	200
C8423	96hr	3	17.2979	18.8924	19.1220	0.2296	0.2584	20	77.40	4.64	3.26	6	0.045	151.1	87214920	0.000	85.08	85.08
C8423	96hr	3	17.2979	18.8924			0.2546	19	74.63	1.87	3.26	6	0.045	151.1	87214920	0.000	85.08	85.08
C8424	96hr	3	17.3367	18.9456	19.1454	0.1998	0.2541	18	70.84	0.00	0.00	0	0.000	146.3	84444360	0.000	#DIV/0!	#DIV/0!
C8424	96hr	3	17.3367	18.9456			0.2574	18	69.93	0.00	0.00	0	0.000	146.3	84444360	0.000	#DIV/0!	#DIV/0!
C8427	96hr	4	17.2602	18.8623	19.0745	0.2122	0.2552	18	70.53	0.00	1.49	3	0.022	186.8	107820960	0.000	200	200
C8427	96hr	4	17.2602	18.8623			0.2593	20	77.13	2.98	1.49	3	0.022	186.8	107820960	0.000	200	200
C8428	96hr	4	17.2374	18.8320	19.0527	0.2207	0.2564	20	78.00	3.85	3.64	7	0.052	173.8	100317360	0.000	11.64	11.64
C8428	96hr	4	17.2374	18.8320			0.2578	20	77.58	3.43	3.64	7	0.052	173.8	100317360	0.000	11.64	11.64
C8429	96hr	4	17.2846	18.8666	19.1044	0.2378	0.2557	19	74.31	0.16	4.02	7	0.053	185.1	106839720	0.000	192.28	192.28
C8429	96hr	4	17.2846	18.8666			0.2560	21	82.03	7.88	4.02	7	0.053	185.1	106839720	0.000	192.28	192.28
C8430	96hr	4	17.4329	19.0278	19.2138	0.1860	0.2542	18	70.81	0.00	0.00	0	0.000	187.6	108282720	0.000	#DIV/0!	#DIV/0!
C8430	96hr	4	17.4329	19.0278			0.2566	17	66.25	0.00	0.00	0	0.000	187.6	108282720	0.000	#DIV/0!	#DIV/0!

Dosing solution S.A.= 0.26 µCi/mg= 577200 DPM/mg  
 BKG= 237 DPM/g Female 96hr  
 BKG= 221 DPM/g Male 96hr

## Blood radioactivity

Animal ID	Time Pt.	Group	Tare + Solubilizer		Tare + Blood wt.		Rep.	Conc.	DPM/s/g corrected	Avg. DPM/g	BW (g)	DPM/rat (blood)	Conc. ug blood	Avg. ugEq/g blood	Group Avg ug/g blood	Dose (mg)	Dose (DPM)	% Dose	% RR	F
			Wt. (g)	Wt. (g)	Wt. (g)	Wt. (g)														
C8419	96hr	1/F	17.8308	17.9312	0.1004	26	258.96	NA	NA	NA	146.1	NA	NA	NA	NA	0	0	NA	NA	
C8419	96hr	1/F	17.9635	18.0766	0.1131	25	221.04	NA	NA	NA	146.1	NA	NA	NA	NA	0	0	NA	NA	
C8420	96hr	1/F	17.9514	18.0713	0.1199	26	216.85	NA	NA	NA	148.5	NA	NA	NA	NA	0	0	NA	NA	
C8420	96hr	1/F	17.9911	18.1109	0.1198	30	250.42	NA	NA	NA	148.5	NA	NA	NA	NA	0	0	NA	NA	
C8425	96hr	2/M	na	na	0.1266	31	244.87	NA	NA	NA	184.6	NA	NA	NA	NA	0	0	NA	NA	
C8425	96hr	2/M	na	na	0.1524	31	203.41	NA	NA	NA	184.6	NA	NA	NA	NA	0	0	NA	NA	
C8426	96hr	2/M	17.7744	17.8993	0.1249	27	216.17	NA	NA	NA	193.0	NA	NA	NA	NA	0	0	NA	NA	
C8426	96hr	2/M	17.6989	17.8134	0.1145	25	218.34	NA	NA	NA	193.0	NA	NA	NA	NA	0	0	NA	NA	
C8421	96hr	3/F	17.8682	17.9938	0.1256	26	207.01	0.00	0.00	0.00	143.9	0.00	0.000	0.000	0.000	149.3	86175960	0.000	#DIV/0!	
C8421	96hr	3/F	17.9951	18.1138	0.1187	27	227.46	0.00	0.00	0.00	143.9	0.00	0.000	0.000	0.000	149.3	86175960	0.000	#DIV/0!	
C8422	96hr	3/F	17.8648	17.9923	0.1275	30	235.29	0.00	0.00	0.00	146.0	0.00	0.000	0.000	0.000	159.5	92063400	0.000	#DIV/0!	
C8422	96hr	3/F	17.7716	17.8915	0.1199	26	216.85	0.00	0.00	0.00	146.0	0.00	0.000	0.000	0.000	159.5	92063400	0.000	#DIV/0!	
C8423	96hr	3/F	na	na	0.1415	25	176.68	0.00	0.00	0.00	147.6	0.00	0.000	0.000	0.000	151.1	87214920	0.000	#DIV/0!	
C8423	96hr	3/F	na	na	0.2076	25	120.42	0.00	0.00	0.00	147.6	0.00	0.000	0.000	0.000	151.1	87214920	0.000	#DIV/0!	
C8424	96hr	3/F	17.8346	17.9543	0.1197	27	225.56	0.00	0.00	0.00	152.7	0.00	0.000	0.000	0.000	146.3	84444360	0.000	#DIV/0!	
C8424	96hr	3/F	17.7714	17.8943	0.1229	26	211.55	0.00	0.00	0.00	152.7	0.00	0.000	0.000	0.000	146.3	84444360	0.000	#DIV/0!	
C8427	96hr	4/M	na	na	0.1266	24	189.57	0.00	0.00	0.00	185.0	0.00	0.000	0.000	0.000	186.8	107820960	0.000	#DIV/0!	
C8427	96hr	4/M	na	na	0.1449	26	179.43	0.00	0.00	0.00	185.0	0.00	0.000	0.000	0.000	186.8	107820960	0.000	#DIV/0!	
C8428	96hr	4/M	17.7782	17.9032	0.1250	27	216.00	0.00	0.00	0.00	192.4	0.00	0.000	0.000	0.000	173.8	100317360	0.000	200	
C8428	96hr	4/M	17.7852	17.9049	0.1197	30	250.63	29.93	14.96	192.4	329.80	0.052	0.026	0.026	0.000	173.8	100317360	0.000	200	
C8429	96hr	4/M	na	na	0.1277	31	242.76	22.06	11.03	184.8	233.49	0.038	0.019	0.019	0.000	185.1	106839720	0.000	200	
C8429	96hr	4/M	na	na	0.1302	28	215.05	0.00	0.00	0.00	184.8	0.00	0.000	0.000	0.000	185.1	106839720	0.000	200	
C8430	96hr	4/M	na	na	0.1031	29	281.28	60.58	61.09	202.9	704.21	0.105	0.106	0.106	0.038	187.6	108282720	0.001	1.67	
C8430	96hr	4/M	na	na	0.0921	26	282.30	61.80	61.09	202.9	716.09	0.107	0.106	0.106	0.038	187.6	108282720	0.001	1.67	

Counts in bold letters are repeats due to non-uniformity of sampling

Dosing solution S.A.= 0.26 µCi/mg= 577200 DPMs/mg

BKG= 94 DPM/g Female 96hr  
BKG= 89 DPM/g Male 96hr

## Carcass

Animal ID	Time Pt.	Group	Tare Wt.(g)	Tare + TEAH Wt. (g)		Tare + Sample + Solubilizer (g)		Homog. Wt. (g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g correct.	Avg. DPM's/g in sample	Total DPM in sample	Conc. ug Eq/g carcass	Dose (mg) carcass	Dose (DPM) carcass	% Dose	% RR	F
				WT. (g)	WT. (g)	WT. (g)	WT. (g)													
C8419	96hr	1	384.2	579.8	698.5	118.7	314.3	0.2706	25	92.39	92.39	NA	NA	NA	NA	0	0	NA	NA	
C8419	96hr	1						0.2819	26	92.23	92.23	NA	NA	NA	NA	0	0	NA	NA	
C8420	96hr	1	383.8	568.3	689.1	120.8	305.3	0.2791	26	93.16	93.16	NA	NA	NA	NA	0	0	NA	NA	
C8420	96hr	1						0.2841	26	98.45	98.45	NA	NA	NA	NA	0	0	NA	NA	
C8425	96hr	2	383.9	569.2	716.6	147.4	332.7	0.2724	22	80.76	80.76	NA	NA	NA	NA	0	0	NA	NA	
C8425	96hr	2						0.2687	25	93.04	93.04	NA	NA	NA	NA	0	0	NA	NA	
C8426	96hr	2	385.3	578.3	731.4	153.1	346.1	0.2949	24	81.38	81.38	NA	NA	NA	NA	0	0	NA	NA	
C8426	96hr	2						0.273	27	98.90	98.90	NA	NA	NA	NA	0	0	NA	NA	
C8421	96hr	3	384.6	575.9	694.8	118.9	310.2	0.2655	31	116.76	116.76	22.71	15.51	4812	0.070	149.3	86175960	0.006	92.72	
C8421	96hr	3						0.2735	28	102.38	102.38	8.32	0.00	0	0.000	149.3	86175960	0.000	#DIV/0!	
C8422	96hr	3	384.2	576.1	694.7	118.6	310.5	0.2907	27	92.88	92.88	0.00	0.00	0	0.000	159.5	92063400	0.000	#DIV/0!	
C8422	96hr	3						0.2846	25	87.84	87.84	0.00	0.00	0	0.000	159.5	92063400	0.000	#DIV/0!	
C8423	96hr	3	385.1	572.5	691.5	119.0	306.4	0.2781	29	104.28	104.28	10.22	8.84	2707	0.039	151.1	87214920	0.003	31.41	
C8423	96hr	3						0.266	27	101.50	101.50	7.45	8.84	2707	0.039	151.1	87214920	0.003	31.41	
C8424	96hr	3	385.0	567.1	690.6	123.5	305.6	0.275	28	101.82	101.82	7.76	8.88	2652	0.037	146.3	84444360	0.003	21.08	
C8424	96hr	3						0.2605	27	103.65	103.65	9.59	8.88	2652	0.037	146.3	84444360	0.003	21.08	
C8427	96hr	4	384.1	570.4	717.1	146.7	333.0	0.313	38	121.41	121.41	32.88	33.95	11306	0.134	186.8	107820960	0.010	6.3	
C8427	96hr	4						0.2833	35	123.54	123.54	35.02	33.95	11306	0.134	186.8	107820960	0.010	6.3	
C8428	96hr	4	383.6	579.5	733.5	154.0	349.9	0.2914	27	92.66	92.66	4.13	2.07	723	0.008	173.8	100317360	0.001	200	
C8428	96hr	4						0.3334	28	83.98	83.98	0.00	2.07	723	0.008	173.8	100317360	0.001	200	
C8429	96hr	4	384.3	580.8	731.9	151.1	347.6	0.2796	25	89.41	89.41	0.89	3.61	1253	0.014	185.1	106839720	0.001	150.57	
C8429	96hr	4						0.3374	32	94.84	94.84	6.32	3.61	1253	0.014	185.1	106839720	0.001	150.57	
C8430	96hr	4	384.4	580	740.9	160.9	356.5	0.2625	26	99.05	99.05	10.53	11.02	3928	0.042	187.6	108282720	0.004	8.96	
C8430	96hr	4						0.2899	29	100.03	100.03	11.51	11.02	3928	0.042	187.6	108282720	0.004	8.96	

Dosing solution S. 0.26 µCi/mg= 577200 DPMs/mg  
 BKG= 39 DPM/g Female 96hr  
 BKG= 40 DPM/g Male 96hr

Animal ID	Time Pt.	Group	Tare Wt.(g)	Sample Wt.(g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Avg. DPM's/g	Total DPM in sample	Conc. ug Eq/g sample	Dose (mg)	Dose (DPM)	% Dose	% RR	F
C8419	96hr	1	170.6	244.6	74	0.4414	19	43.04	NA	NA	NA	0	0	0	NA	NA
C8419	96hr	1				0.4522	17	37.59	NA	NA	NA	0	0	0	NA	NA
C8420	96hr	1	171.7	229.5	57.8	0.4435	17	38.33	NA	NA	NA	0	0	0	NA	NA
C8420	96hr	1				0.4505	17	37.74	NA	NA	NA	0	0	0	NA	NA
C8425	96hr	2	170.7	225.6	54.9	0.4372	18	41.17	NA	NA	NA	0	0	0	NA	NA
C8425	96hr	2				0.4417	17	38.49	NA	NA	NA	0	0	0	NA	NA
C8426	96hr	2	172.4	251.5	79.1	0.4455	19	42.65	NA	NA	NA	0	0	0	NA	NA
C8426	96hr	2				0.4481	17	37.94	NA	NA	NA	0	0	0	NA	NA
C8421	96hr	3	171.3	276.9	105.6	0.4445	18	40.49	1.32	589	0.01	149.3	86175960	0.001	152.71	
C8421	96hr	3				0.4489	22	49.01	9.83	589	0.01	149.3	86175960	0.001	152.71	
C8422	96hr	3	172.1	252.4	80.3	0.4471	20	44.73	5.56	329	0.01	159.5	92063400	0.000	71.26	
C8422	96hr	3				0.4544	19	41.81	2.64	329	0.01	159.5	92063400	0.000	71.26	
C8423	96hr	3	172.2	259.2	87	0.4475	18	40.22	1.05	71	0.00	151.1	87214920	0.000	55.25	
C8423	96hr	3				0.4526	18	39.77	0.59	71	0.00	151.1	87214920	0.000	55.25	
C8424	96hr	3	171	251.5	80.5	0.4375	24	54.86	15.68	1417	0.03	146.3	84444360	0.002	21.79	
C8424	96hr	3				0.4430	26	58.69	19.51	1417	0.03	146.3	84444360	0.002	21.79	
C8427	96hr	4	172.3	249.5	77.2	0.4354	23	52.82	12.76	1013	0.02	186.8	107820960	0.001	5.51	
C8427	96hr	4				0.4482	24	53.55	13.49	1013	0.02	186.8	107820960	0.001	5.51	
C8428	96hr	4	172.0	266.3	94.3	0.4431	24	54.16	14.10	1010	0.02	173.8	100317360	0.001	63.31	
C8428	96hr	4				0.4432	21	47.38	7.32	1010	0.02	173.8	100317360	0.001	63.31	
C8429	96hr	4	172.0	276.2	104.2	0.4417	21	47.54	7.48	390	0.01	185.1	106839720	0.000	200	
C8429	96hr	4				0.4477	17	37.97	0.00	390	0.01	185.1	106839720	0.000	200	
C8430	96hr	4	171.5	278.2	106.7	0.4459	15	33.64	0.00	0	0.00	187.6	108282720	0.000	#DIV/0!	
C8430	96hr	4				0.4457	16	35.90	0.00	0	0.00	187.6	108282720	0.000	#DIV/0!	

% Dose Excreted in urine, feces, GI content, expired air, cage rinse and CO<sub>2</sub> (KOH)

## Fischer 344, Females

Animal I	Group	Urine	Feces	Content of GI tract	Cage rinse	Expired air	CO <sub>2</sub> (KOH)	% Dose excreted
C8421	3	0.014	86.003	0.000	0.001	0.004	0.001	86.022
C8422	3	0.014	84.874	0.001	0.000	0.002	0.003	84.895
C8423	3	0.009	85.582	0.001	0.000	0.001	0.000	85.594
C8424	3	0.013	87.967	0.000	0.002	0.001	0.002	87.985

Animal I	Group	Urine	Feces	Content of GI tract	Cage rinse*	Expired air	O <sub>2</sub> (KOH)	% Dose excreted
C8421	3	0.014	86.003	0.000	0.000	0.004	0.000	86.021
C8422	3	0.014	84.874	0.001	0.000	0.002	0.000	84.891
C8423	3	0.009	85.582	0.001	0.000	0.001	0.000	85.593
C8424	3	0.013	87.967	0.000	0.000	0.001	0.000	87.981
Average		0.012	86.107	0.001	0.000	0.002	0.000	86.122
SEM		0.001	0.663	0.000	0.000	0.001	0.000	0.662

## Fischer 344, Males

Animal I	Group	Urine	Feces	Content of GI tract	Cage rinse	Expired air	CO <sub>2</sub> (KOH)	% Dose excreted
C8427	4	0.016	88.228	0.002	0.001	0.005	0.001	88.252
C8428	4	0.016	89.754	0.000	0.001	0.003	0.000	89.775
C8429	4	0.015	90.839	0.000	0.000	0.003	0.001	90.858
C8430	4	0.015	89.622	0.000	0.000	0.003	0.001	89.641

Animal I	Group	Urine	Feces	Content of GI tract*	Cage rinse	Expired air	CO <sub>2</sub> (KOH)	% Dose excreted
C8427	4	0.016	88.228	0.000	0.001	0.005	0.001	88.251
C8428	4	0.016	89.754	0.000	0.001	0.003	0.000	89.774
C8429	4	0.015	90.839	0.000	0.000	0.003	0.001	90.858
C8430	4	0.015	89.622	0.000	0.000	0.003	0.001	89.641
Average		0.016	89.611	0.000	0.001	0.003	0.001	89.631
SEM		0.000	0.535	0.000	0.000	0.000	0.000	0.535

\* not greater than zero based on statistical analysis

## % Dose recovered in blood, carcass, eyes, fat, spleen, kidneys, liver and GI tract (emptied)

## Fischer 344, Females

Animal I	Group	Blood	Carcass	Eyes	Fat	Spleen	Kidneys	Liver	GI tract (emptied)	% Dose recovered in tissues & carcasses
C8421	3	0.000	0.006	0.000	0.000	0.000	0.000	0.000	0.000	0.007
C8422	3	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001
C8423	3	0.000	0.003	0.000	0.000	0.000	0.000	0.000	0.000	0.004
C8424	3	0.000	0.003	0.000	0.000	0.000	0.000	0.000	0.000	0.004

Animal I	Group	Blood*	Carcass	Eyes*	Fat*	Spleen	Kidneys	Liver	GI tract (emptied)	%Dose recovered in tissues & carcasses
C8421	3	0.000	0.006	0.000	0.000	0.000	0.000	0.000	0.000	0.007
C8422	3	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001
C8423	3	0.000	0.003	0.000	0.000	0.000	0.000	0.000	0.000	0.004
C8424	3	0.000	0.003	0.000	0.000	0.000	0.000	0.000	0.000	0.004
Average		0.000	0.003	0.000	0.000	0.000	0.000	0.000	0.000	0.004
SEM		0.000	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.001

## Fischer 344, Males

Animal I	Group	Blood	Carcass	Eyes	Fat	Spleen	Kidneys	Liver	GI tract (emptied)	%Dose recovered in tissues & carcasses
C8427	4	0.000	0.010	0.000	0.000	0.000	0.000	0.000	0.001	0.011
C8428	4	0.000	0.001	0.000	0.000	0.000	0.000	0.001	0.000	0.002
C8429	4	0.000	0.001	0.000	0.000	0.000	0.000	0.000	0.000	0.002
C8430	4	0.001	0.004	0.000	0.000	0.000	0.000	0.000	0.000	0.005

Animal I	Group	Blood*	Carcass*	Eyes	Fat*	Spleen	Kidneys	Liver	GI tract (emptied)	%Dose recovered in tissues & carcasses
C8427	4	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001
C8428	4	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.000	0.001
C8429	4	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001
C8430	4	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001
Average		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001
SEM		0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000

\* not greater than zero based on statistical analysis

## % Dose Recovered (all samples)

## Fischer 344, Females

## Fischer 344, Males

Animal ID	Group	% Dose excreted	% Dose recovered in tissues	% Dose recovered in carcasses	Total Recovery (%)	Animal ID	Group	% Dose excreted	% Dose recovered in tissues	% Dose recovered in carcasses	Total Recovery (%)
C8421	3	86.021	0.001	0.006	86.027	C8427	4	88.251	0.001	0.000	88.251
C8422	3	84.891	0.001	0.000	84.892	C8428	4	89.774	0.001	0.000	89.776
C8423	3	85.593	0.001	0.003	85.597	C8429	4	90.858	0.001	0.000	90.859
C8424	3	87.981	0.001	0.003	87.985	C8430	4	89.641	0.001	0.000	89.642
<b>Average</b>		<b>86.122</b>	<b>0.001</b>	<b>0.003</b>	<b>86.125</b>	<b>Average</b>		<b>89.631</b>	<b>0.001</b>	<b>0.000</b>	<b>89.632</b>
<b>SEM</b>		<b>0.662</b>	<b>0.000</b>	<b>0.001</b>	<b>0.663</b>	<b>SEM</b>		<b>0.535</b>	<b>0.000</b>	<b>0.000</b>	<b>0.535</b>
<b>SDEV</b>		<b>1.324</b>	<b>0.000</b>	<b>0.002</b>	<b>1.325</b>	<b>SDEV</b>		<b>1.070</b>	<b>0.000</b>	<b>0.000</b>	<b>1.070</b>

\* not greater than zero based on statistical analysis

## % Dose excreted in feces and total dose recovery corrected for processing efficiency

## Fischer 344, Females

Animal ID	Group	% Dose recovered in feces	Corrected % recovered in feces <sup>1</sup>	Corrected % dose excreted	Total recovery (%)	Corrected Total recovery <sup>1</sup> (% Dose)	Feces recovery (%)
C8421	3	86.003	93.482	93.499	86.027	93.506	99.97
C8422	3	84.874	92.254	92.271	84.892	92.272	99.98
C8423	3	85.582	93.024	93.035	85.597	93.039	99.98
C8424	3	87.967	95.617	95.630	87.985	95.635	99.98
<b>Average</b>		<b>86.107</b>	<b>93.594</b>	<b>93.609</b>	<b>86.125</b>	<b>93.613</b>	<b>99.98</b>
<b>SEM</b>		<b>0.663</b>	<b>0.720</b>	<b>0.720</b>	<b>0.663</b>	<b>0.720</b>	
<b>SDEV</b>		<b>1.325</b>	<b>1.440</b>	<b>1.440</b>	<b>1.325</b>	<b>1.441</b>	

## Fischer 344, Males

Animal ID	Group	% Dose recovered in feces	Corrected % recovered in feces <sup>1</sup>	Corrected % dose excreted	Total recovery (%)	Corrected Total recovery <sup>1</sup> (% Dose)	Feces recovery (%)
C8427	4	88.228	95.900	95.923	88.251	95.923	99.98
C8428	4	89.754	97.559	97.579	89.776	97.580	99.98
C8429	4	90.839	98.738	98.757	90.859	98.758	99.98
C8430	4	89.622	97.415	97.434	89.642	97.435	99.98
<b>Average</b>		<b>89.611</b>	<b>97.403</b>	<b>97.423</b>	<b>89.632</b>	<b>97.424</b>	<b>99.98</b>
<b>SEM</b>		<b>0.535</b>	<b>0.582</b>	<b>0.581</b>	<b>0.535</b>	<b>0.581</b>	
<b>SDEV</b>		<b>1.071</b>	<b>1.164</b>	<b>1.163</b>	<b>1.070</b>	<b>1.163</b>	

<sup>1</sup>) Percent dose recovered in feces was corrected for the sample processing efficiency  
Total recovery= % dose excreted + % dose recovered in carcasses and tissues

**DOW CORNING CORPORATION  
HEALTH & ENVIRONMENTAL SCIENCES  
CONTRIBUTING SCIENTIST REPORT**

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**Title:** Qualitative Analysis of the Radioactivity Profile of Fecal Homogenates from Male and Female Fischer 344 Rats Following a 1000mg/kg Oral Gavage Dose of <sup>14</sup>C-Polydimethylsiloxane, 350cst

**Study No.:** 9345

**Test Article:** <sup>14</sup>C-Polydimethylsiloxane, 350cst (<sup>14</sup>C-PDMS)

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**Contributing Scientist Report Completion Date:** November 6, 2001

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## ABSTRACT

The objective of the work reported in this contributing scientist report was to evaluate the radioactivity profile from feces collected from male and female Fischer 344 rats following an oral gavage dose of approximately 1000 mg  $^{14}\text{C}$ -PDMS, 350cst/kg body weight. Feces were collected from animals housed in Roth style glass metabolism cages designed for the separate collection of expired volatiles, expired  $^{14}\text{CO}_2$ , urine, and feces. The feces were homogenized with Milli-Q water in a 3:1 v:w ratio of water to feces. Aliquots of the fecal homogenates were solubilized and analyzed by liquid scintillation counting (LSC) as part of the protocol to determine the radioactivity content in each sample. After reviewing the results from these analyses, the samples having radioactivity contents greater than 100,000 dpm/g fecal homogenate were selected for extraction. Aliquots of the 12-hour, 24-hour and 48-hour fecal homogenates were selected and initially extracted with tetrahydrofuran and analyzed by high performance liquid chromatography with radiochemical detection using a gel-permeation column. The amount of radioactivity extracted was compared to the amount of radioactivity found by solubilization and liquid scintillation analysis of the fecal homogenates in order to determine the extraction efficiency. The resulting extraction efficiencies from the tetrahydrofuran extraction averaged 77%, 85%, and 73% for 12-, 24-, and 48-hour fecal homogenate extracts, respectively. The tetrahydrofuran extracts were then analyzed by HPLC with radiometric detection for a qualitative determination of the profile of radioactivity present in the fecal homogenate extracts. The results of these analyses of all samples and at all time points gave similar radioactivity profiles as a solvent standard of 350 cSt PDMS fluid as well as matrix standards containing 350cSt PDMS fluid (extracts of spiked control fecal homogenates) indicating that all of the radioactivity present in the fecal homogenates was parent 350cSt PDMS. Several additional experiments were performed in order to improve the extraction efficiencies. Results of these experiments indicated that PDMS binds to feces after frozen storage and this bound PDMS is un-extractable in a one solvent extraction. However, the radioactivity can still be quantified by solubilization and liquid scintillation analysis, although, some loss may occur that can be attributed to loss of PDMS to the glass container.

An additional dosing experiment was done where samples were immediately processed for extraction with toluene, and subsequently also with tetrahydrofuran (THF) in order to avoid the sample storage/freeze-thaw instability seen previously. These results showed that extraction of PDMS, 350cst from feces obtained from dosed animals could be done quantitatively (92%) with

a two solvent extraction consisting of toluene first and then THF and that the radioactivity present in the feces was confirmed to be unchanged PDMS, 350cst.

### APPROVAL SIGNATURES

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This report consists of pages 1 through 73 including Tables 1-10, Figures 1-3, and Attachments A-E.

Debra A. McNett

Nov. 6, 2001

Debra A. McNett., B.S.

Date

Associate Research Specialist

Contributing Scientist

Bioanalytical Support

## OBJECTIVE

The objective of the work reported in this contributing scientist report was to evaluate the radioactivity profile from feces collected from male and female Fischer 344 rats following an oral gavage dose of approximately 1000 mg  $^{14}\text{C}$ -PDMS 350cst/kg body weight.

## EXPERIMENTAL DESIGN

### Introduction

Experimental design and specific information regarding the test article, test system, route of exposure, dose groups, sample collection, and statistical analysis can be found in the body of the main report.

### Sample Processing and Analysis

The results reported in this contributing scientist report pertain to the rats in dose groups 1-4 (Part 1), 7 and 8 (Part 3).

### Part 1 – Groups 1-4

Feces samples and contents of GI tracts were weighed following collection and processed for radioactivity analysis by liquid scintillation counting (LSC). The feces and GI content samples were homogenized with Milli-Q water at 3:1 v:w ratio of water to feces or GI content. The aliquots of the fecal or GI content homogenates were solubilized using 35% TEAH and processed for radioactivity analysis by LSC. The results of these analyses were reviewed to determine which samples had greater than 100,000 dpm/g homogenate which would give sufficient sensitivity upon analysis. Only the 12-hr, 24-hr and 48-hr fecal homogenate samples had sufficient radioactivity levels greater than 100,000 dpm/g homogenate.

Aliquots of the 12-hour, 24-hour and 48- hour fecal homogenates were initially extracted with tetrahydrofuran (THF) three times combining the three extracts for each sample. In addition quality control (QC) samples were prepared by spiking varying amounts of the  $^{14}\text{C}$ -PDMS dosing solution into control fecal homogenate samples. These QC samples were then extracted with THF along with the study samples at the same time using the same procedure. A qualitative assessment was then made of the THF extracts using high performance liquid chromatography (HPLC) with radiochemical detection on a gel-permeation column in order to determine if the radioactivity present in the feces was

unchanged  $^{14}\text{C}$ -PDMS. In addition, the amount of radioactivity extracted into the THF extracts was determined by LSC. The amount of radioactivity found in the extracts was then compared to the amount of radioactivity found by solubilization and liquid scintillation analysis of the fecal homogenates in order to determine the extraction efficiency. For the QC samples, the amount of radioactivity present in the THF extracts was compared to the amount of radioactivity spiked into the control fecal homogenates in order to determine the extraction efficiency.

After evaluation of the extraction efficiencies found from the THF extraction of the QC samples and the fecal homogenate samples, the protocol was amended to include extraction of the samples with toluene in order to try to attain higher extraction efficiencies for the QC samples and fecal homogenate samples. After some method development with toluene as the extraction solvent with QC samples, aliquots of the 12-hour, 24-hour and 48-hour fecal homogenates were extracted with toluene following the THF extraction procedure (3 extractions) with the exception that toluene was used as the extraction solvent instead of THF. As before, QC samples were prepared by spiking varying amounts of the  $^{14}\text{C}$ -PDMS dosing solution into control fecal homogenate samples. These QC samples were then extracted along with the study samples at the same time using the same toluene extraction procedure. A qualitative assessment was then made of the toluene extracts using high performance liquid chromatography (HPLC) with radiochemical detection on a gel-permeation column in order to determine if the radioactivity present in the feces was unchanged  $^{14}\text{C}$ -PDMS in the same manner as before with the THF extracts. In addition, the amount of radioactivity extracted into the toluene extracts was determined by LSC. The amount of radioactivity found in the extracts was again compared to the amount of radioactivity found previously by solubilization and liquid scintillation analysis of the fecal homogenates in order to determine the extraction efficiency. For the QC samples, the amount of radioactivity present in the toluene extracts was compared to the amount of radioactivity spiked into the control fecal homogenates in order to determine the extraction efficiency.

Upon investigation of the extraction efficiencies, additional aliquots of the 12-hour, 24-hour and 48-hour fecal homogenate samples were taken. Single aliquots of each sample were extracted a second time with toluene and the extracts were analyzed by liquid scintillation analysis. Duplicate aliquots of the same samples were also taken at the same time, solubilized with 35% TEAH and analyzed by liquid scintillation analysis.

Additional method development with fecal sample spikes was initiated to determine the cause of the low extraction efficiencies that were seen with the previous sample experiments. Two concentrations of  $^{14}\text{C}$ -PDMS spiked samples and one control sample were prepared for analysis on the same day by each of two different procedures (six samples total). In the first procedure, control feces were homogenized. The control feces homogenate was separated into three fecal homogenate samples in sizes similar to those collected as study samples (approximately 6g feces & 18g homogenate total) and into the same jars as used for the study samples. The samples were then fortified with 0g, 0.033g, or 0.058g of  $^{14}\text{C}$ -PDMS test article. These samples were then mixed by vortexing for approximately 5 minutes. In the second procedure, three control fecal pellet samples (non-homogenized) in sizes similar to those collected as study samples (approximately 6g) and the same jars as used for study samples were fortified with 0g, 0.0392g or 0.0598g of  $^{14}\text{C}$ -PDMS test article. The six jars of fecal samples (both homogenized and non-homogenized) were then stored frozen at  $-80\pm 10^\circ\text{C}$  overnight. The next day all six samples were removed from frozen storage and allowed to thaw on ice. The three samples that had not been homogenized prior to spiking, were then homogenized (see deviation). Aliquots were removed from each of the six jars for extraction with toluene (3 times) and direct analysis by liquid scintillation analysis of the toluene extract. In addition, aliquots of the six fecal homogenate samples were removed from each jar for solubilization with TEAH and liquid scintillation analysis of the solubilized samples. The six jars were placed back in frozen storage at  $-80\pm 10^\circ\text{C}$  for 30 days. After frozen storage for 30 days, the six jars were removed from storage, allowed to thaw on ice, and aliquots were removed from each of the six jars for extraction with toluene (3 times) and analysis by liquid scintillation analysis as described previously. At the same time, aliquots were again removed from each jar for solubilization and subsequent liquid scintillation analysis.

### Part 3 – Groups 7-8

In order to fully account for all of the radioactivity present in the feces, a new dosing experiment was initiated. Details of the dosing and animal care for this additional experiment can be found in the body of the main report. The feces samples collected from the two additional male and two additional females dosed in this additional experiment were immediately homogenized with Milli-Q water at 3:1 v:w ratio of water to feces with a tissue homogenizer following collection at the 12-hour, 24-hour and 48-hour timepoint on each day. Immediately after the feces samples were homogenized, aliquots were taken for

solubilization with 35% TEAH and subsequent LSC analysis as well as for extraction with toluene (3x) and subsequent analysis by HPLC/RAD and LSC. At no time were the samples stored frozen or thawed, instead they were processed immediately following collection in order to avoid the extraction efficiency problems seen in Part 1 of the experiment. As was done in Part 1, at the same time, QC samples were prepared by spiking control fecal homogenate samples with varying amounts of <sup>14</sup>C-PDMS and processed and analyzed in the same manner as the samples. Upon analysis of the toluene extraction efficiencies found for these samples by LSC analysis, the fecal residues remaining from the toluene extraction were extracted with THF (3x), followed by solubilization of the remaining fecal residue with 35% TEAH to determine the unextractable radioactivity remaining. QC's were also made for THF extraction and analyzed along with the samples. Aliquots of the THF extract as well as the solubilized fecal residue remaining were analyzed by LSC for radioactivity determination. Aliquots of both the toluene and THF extracts were analyzed separately by HPLC/RAD as previously described for a qualitative assessment of the radioactivity present.

The following table details the HPLC conditions used for analysis in both Parts 1 and 3:

Table 1. HPLC Equipment and Parameters for Fecal Extract Analysis	
Equipment/Parameter	System Specifications
Pump	Hewlett Packard 1050 Quaternary HPLC Pump
Detector	Packard Radiomatic A-515A
Autosampler	Hewlett Packard 1050 Series Autosampler
Data Acquisition	IBM Personal Computer 350 Hewlett Packard Chemstation for LC Rev. A.05.01 Packard Radiomatic FLO-ONE/Data Control Series A-500, Version 3.5.5
Analytical Column	Plgel 5µm 100A column, 300mm x 7.5mm ID
Mobile Phase	100% Tetrahydrofuran, or 100% Toluene depending on which extraction solvent was used
Run Time	60 minutes
Injection Volume	100 µL
Flow Rate	HPLC at 1.0 mL/minute Radiomatic at 3.0 mL/minute
Liquid Scintillation Cocktail	Ultima Flo M

All remaining sample processing and analysis parameters can be found in the body of the main report.

## DEVIATIONS

1. An SOP deviation was reported from SOP #PKM.2.16 when the non-homogenized (homogenized after spiking) samples were homogenized. The weights of the total sample of feces plus the Milli-Q water added for homogenization were not recorded for these three samples. As a result, the concentration (dpm/g of homogenate) of  $^{14}\text{C}$ -PDMS could not be exactly gravimetrically calculated from the dpm/g of feces. A theoretical dilution of 0.25 (1/4) was used as the SOP requires dilution of the feces 1:3 w:v with Milli-Q water. In the original homogenizations of the study samples, where the final weights were properly taken as specified in the SOP, the average dilution was 0.2516. Based on this, it is assumed that using the theoretical dilution of 0.25 does not make the final dpm/g homogenate significantly different than it would have been if the exact dilution was known. As a result, this assumption that had to be made does not adversely affect the study outcome.

## RESULTS AND DISCUSSION

Individual extraction efficiency results from the THF extraction of the 12-, 24-, and 48-hour fecal homogenates as well as the QC samples can be found in table 2 and all calculations can be found in attachment A. The THF extraction efficiencies averaged 77%, 85%, and 73% for 12-, 24-, and 48-hour fecal homogenate extracts, respectively and 78% for the QC samples. The THF extracts were then analyzed by HPLC with radiometric detection for a qualitative determination of the profile of radioactivity present in the fecal homogenate extracts. The results of these analyses of all samples and at all time points gave similar radioactivity profiles as a THF solvent standard of 350 cst PDMS fluid as well as the QC samples indicating that all of the THF extractable radioactivity present in the fecal homogenates was parent 350cSt PDMS. Example radio-chromatograms of a 12-hour male, 12-hour female, and a QC fecal homogenate THF extracts are presented in figure 1. Example radio-chromatograms of THF solvent standards containing  $^{14}\text{C}$ -PDMS or  $^{14}\text{C}$ -octamethylcyclotetrasiloxane ( $^{14}\text{C}$ -D<sub>4</sub>) are presented in figure 2.

Due to the less than optimum extraction efficiencies found with the THF extractions for both the study samples when compared to the solubilizations and analyses, and for the QC samples,

method development work was initiated to try to find a more suitable extraction solvent. It was determined as a result of this method development work (see attachment B) that extraction of QC samples with toluene resulted in extraction efficiencies closer to 100%. As a result, a protocol amendment was written to include extraction of the study samples with toluene in order to account for a larger percentage of the total radioactivity. Individual extraction efficiency results from the toluene extraction of the 12-, 24-, and 48-hour fecal homogenates as well as the QC samples can be found in table 3 and calculations can be found in attachment B. The toluene extraction efficiencies averaged 72%, 81%, and 50% for the 12-, 24-, and 48-hour fecal homogenate extracts, respectively, and 95% for the QC samples. The toluene extracts were also analyzed by HPLC with radiometric detection for a qualitative determination of the profile of radioactivity present in the fecal homogenate extracts. The results of these analyses of all samples and at all time points gave similar radioactivity profiles as toluene extracted QC samples indicating that all of the toluene extractable radioactivity present in the fecal homogenates was parent 350cSt PDMS. Example radio-chromatograms of a 12-hour male, 12-hour female, and a QC fecal homogenate toluene extracts are presented in figure 3.

Upon finding even lower extraction efficiencies for the toluene extractions of the study samples when compared to the original solubilizations and LSC analyses than observed with the THF extractions, even though the QC samples run along with these samples showed quantitative extraction (95%), it was postulated that the PDMS was perhaps migrating and binding to the glass jars after prolonged frozen storage of aqueous fecal homogenate. The initial extractions with THF were performed on 3/28/00 and the toluene extractions were initiated on 6/13/00. In order to test this hypothesis, aliquots of the 12-, 24-, and 48-hour samples were once again taken for toluene extraction and LSC analysis on 8/7/00. In addition, at the same time, aliquots were taken for solubilization and analysis by LSC. Comparisons were made between the analyses of the toluene extractions and the solubilizations done at the same time. Results from these analyses can be found in table 4. Individual results can be found in attachment C. The extraction efficiencies averaged 31%, 43%, and 30% for the 12-, 24-, and 48-hour fecal homogenates when compared to the solubilization and analysis done concurrently. The solubilization analyses done originally (table 2) and done at the same time as this extraction (table 4) were also compared. Results from this comparison can be found in table 5 and individual results can be found in attachment C. The average % recovery (8/7/00 analysis / original analysis x 100) comparing these different times of analyses was 100%. As a result, even though the extraction efficiencies continued to decrease after storage, the amount found upon solubilization and direct LSC analysis stayed the same. Based on these results, it was

presumed that the loss of PDMS upon extraction was either due to un-extractable binding to the fecal components or to degradation of the PDMS to polar products that are un-extractable with toluene.

A spiking experiment was designed to try to further understand the cause of the extraction efficiency losses seen. The experiment consisted of two types of samples as described in the Sample Processing and Analysis section. The first type (homogenized and then spiked) was used to test to see if any loss was found due to migration to the glass jar. The second type (Non-homogenized – spiked and homogenized after) represented how the study samples were handled (the study sample feces were collected and stored frozen prior to homogenization). The samples were then homogenized and aliquots were taken for solubilization in 35% TEAH and extraction in toluene. Aliquots of these six samples (3 homogenized and 3 non-homogenized) were taken after 1 day of frozen storage for analysis by extraction and solubilization. The six homogenized samples were returned to frozen storage for 30 days, at which time, aliquots were again removed for analysis by extraction and solubilization. Extraction efficiencies were determined by comparison to the solubilizations and analyses done concurrently. Results from the extractions and solubilizations performed 1 day and 30 days following spiking can be found in tables 6 and 7, respectively. Individual results including all calculations can be found in attachment D. The average extraction efficiencies of the spiked homogenized feces (compared to solubilization) were 92% after 1 day of storage and 90% after 30 days of storage. The variability for this type of sample was quite high, however, indicating that the homogeneity of the PDMS in the samples that had been homogenized prior to spiking was poor. In spite of this variability, the recoveries indicated that the PDMS was not binding to the feces after homogenization. In contrast, the average extraction efficiencies of the non-homogenized sample (homogenized 1 day after spiking) after 1 day of storage was 84% and 44% after 30 days of storage. The variability was low for these samples indicating that the homogeneity of the PDMS was quite good. The loss after 30 days of storage in these samples that most closely mimic how the study samples were handled could be attributed to binding of the PDMS to the feces that cannot be extracted. This binding apparently cannot be broken through extraction with toluene and it becomes more pronounced with increased storage time. The binding apparently only occurs if the PDMS is initially in direct contact with the fecal pellets, i.e. not diluted with water and homogenized. Another possibility is that the PDMS is degrading with freeze-thaw cycles and the degradation products may be polar and hence not extractable with toluene.

In addition, the solubilization and analyses of these spiked samples were compared after 1 and 30 days of storage to the actual amount of PDMS spiked. These results can be found in table 8. Individual results and all calculations can be found in attachment D. The average radioactivity recovery found by solubilization and LSC analysis of the homogenized samples after 1 day of storage was 104% and after 30 days of storage it was 86%. Again, the variability was high, indicating a problem with homogeneity of the highly hydrophobic PDMS in the aqueous feces homogenate. The average radioactivity recovery from the non-homogenized samples (homogenized after spiking) after solubilization was 92% of the amount spiked after 1 day of storage, and 89% after 30 days of storage. Results from this comparison may indicate that some loss (approximately 10%) can be attributed to loss of the PDMS to the sample processing and binding to the glass container. This has been seen with another hydrophobic siloxane, octamethylcyclotetrasiloxane.<sup>1,2</sup> The efficiency of solubilization and LSC analysis done in the same container without transferring from aqueous samples was previously determined during method development and averaged 104%. These results further indicated that the approximately 10% loss seen for the solubilization processing efficiencies (when an aliquot is transferred from the aqueous sample) can be attributed to binding of the hydrophobic PDMS to the glass container.

In order to fully account for all of the radioactivity present in the feces, a new dosing experiment was initiated. As described in the Sample Processing and Analysis section, the feces collected from the 2 male and 2 female rats from the 12-hour, 24-hour and 48-hour time points were processed for analysis by both extraction with toluene (3x) and solubilization immediately following collection. The results from the toluene extraction of these samples can be found in Table 9 and the results from the extraction of QC samples run alongside these samples can be found in Table 10. Individual results and calculations can be found in attachment E. The extraction of the samples in toluene when compared to the solubilization and LSC analysis gave an average of 77%. Upon this discovery, the remaining fecal residues were extracted with THF (3x). These additional extractions gave an additional average of 14% (also shown in Table 9). The total amount extracted in the two solvents was an average of 92% when compared to the solubilization and LSC analysis. The remaining fecal residue after both solvent extractions was also solubilized and analyzed by LSC and resulted in only an additional average of 1% remaining unextracted. In addition, both the toluene and THF extracts were analyzed by HPLC/RAD separately along with the respective QC sample extracts. The results from these analyses indicated that the radioactivity in both solvents was consistent with <sup>14</sup>C-PDMS as seen in the QC sample extracts (extracts of <sup>14</sup>C-PDMS spiked control feces) as well as with the

respective solvent standards of  $^{14}\text{C}$ -PDMS. This result further supports that the low recoveries were not attributed to degradation to polar metabolites that aren't extractable into the extraction solvent, but rather that the PDMS binds to the feces and requires a two solvent extraction.

### CONCLUSIONS

The results from the analysis of feces samples showed that extraction of PDMS, 350cst from the feces could be done quantitatively with a two solvent extraction (toluene and THF) and that the radioactivity present in the feces was confirmed to be unchanged PDMS, 350cst, indicating that neither metabolism prior to excretion nor degradation upon storage or freeze-thaw cycles is occurring. In addition, some loss (approximately 10%) is seen due to PDMS binding to the glass container.

### ARCHIVE

Study related records, inclusive of, but not limited to sample preparation records, Excel worksheets, and the final report, will be maintained in the archives of Dow Corning Corporation, Midland, MI.

### REFERENCES

1. Seaton, M.J., and K.P. Plotzke (1998) Non-regulated Study: Determination of the Fate of Octamethylcyclotetrasiloxane ( $\text{D}_4$ ) in Selected Rat Tissues. Dow Corning Report # 1998-I0000-44446.
2. McNett, D.A., J.A. Durham, K.P. Plotzke, and M.J. Seaton, (2000) An Evaluation of Methods for Determining  $^{14}\text{C}$ -Octamethylcyclotetrasiloxane ( $^{14}\text{C}$ - $\text{D}_4$ ) Disposition: Sample Stability on Storage. Dow Corning Report # 2000-I0000-48364.

**Table 2. Extraction Efficiency Results from the Extraction of Quality Control (QC) Feces Samples and Study 12-hr, 24-hr, and 48-hr Feces Samples with Tetrahydrofuran (THF) done on 3/28/00 (~ 1 month following collection)**

Animal ID	Time Point	Avg. DPM's/g found from solubilization or spiked (for QC's)	Avg. DPM's/g found from extraction	% Recovery	% Avg. Recovery For Timepoint
<b>THF Extracted Feces QC Samples</b>					
Blank		0	0		
Spike A		9684	7109	73	78
Spike B		354069	296090	84	
Spike C		783444	614390	78	
<b>12-Hour THF Extracted Feces</b>					
C8421	12-hr	3390019	2320117	68	77
C8422	12-hr	2982693	2430921	82	
C8423	12-hr	799785	658305	82	
C8424	12-hr	4148561	3385183	82	
C8427	12-hr	3036609	2205748	73	
C8428	12-hr	4509974	3596152	80	
C8429	12-hr	4474675	3297609	74	
C8430	12-hr	827921	648594	78	
<b>24-Hour THF Extracted Feces</b>					
C8421	24-hr	5822632	5241812	90	85
C8422	24-hr	3460076	2913768	84	
C8423	24-hr	6346882	5456971	86	
C8424	24-hr	2671982	2158175	81	
C8427	24-hr	6309211	5229793	83	
C8428	24-hr	4278045	3630806	85	
C8429	24-hr	3548588	2791073	79	
C8430	24-hr	4247633	3990625	94	
<b>48-Hour THF Extracted Feces</b>					
C8421	48-hr	378824	264870	70	73
C8422	48-hr	96260	72579	75	
C8423	48-hr	431253	338292	78	
C8424	48-hr	89762	66005	74	
C8427	48-hr	475761	352008	74	
C8428	48-hr	259009	181853	70	
C8429	48-hr	81744	52032	64	
C8430	48-hr	223590	167887	75	

**Table 3. Extraction Efficiency Results from the Extraction of Quality Control (QC) Feces Samples and Study 12-hr, 24-hr, and 48-hr Feces Samples with Toluene done 6/13/00 (~ 4 months following collection)**

Animal ID	Time Point	Avg. DPM's/g found from solubilization or spiked (for QC's)	Avg. DPM's/g found from extraction	% Recovery	% Avg. Recovery For Timepoint
<b>Toluene Extracted Feces QC Samples</b>					
Blank		0	0		
Spike A		20513	19230	94	95
Spike B		571882	541766	95	
Spike C		1324648	1260037	95	
<b>12-Hour Toluene Extracted Feces</b>					
C8421	12-hr	3390019	2827024	83	72
C8422	12-hr	2982693	2329299	78	
C8423	12-hr	799785	330950	41	
C8424	12-hr	4148561	2829295	68	
C8427	12-hr	3036609	2037298	67	
C8428	12-hr	4509974	3655997	81	
C8429	12-hr	4474675	3595321	80	
C8430	12-hr	827921	620079	75	
<b>24-Hour Toluene Extracted Feces</b>					
C8421	24-hr	5822632	6548106	112	81
C8422	24-hr	3460076	2783603	80	
C8423	24-hr	6346882	5539934	87	
C8424	24-hr	2671982	1986908	74	
C8427	24-hr	6309211	4036856	64	
C8428	24-hr	4278045	3348558	78	
C8429	24-hr	3548588	2449814	69	
C8430	24-hr	4247633	3510330	83	
<b>48-Hour Toluene Extracted Feces</b>					
C8421	48-hr	378824	230843	61	50
C8422	48-hr	96260	43555	45	
C8423	48-hr	431253	337098	78	
C8424	48-hr	89762	44246	49	
C8427	48-hr	475761	191906	40	
C8428	48-hr	259009	80023	31	
C8429	48-hr	81744	41145	50	
C8430	48-hr	223590	102322	46	

**Table 4. Extraction Efficiency Results from the Extraction of Study 12-hr, 24-hr, and 48-hr Feces Samples with Toluene Compared to Solubilization and Analysis Done Concurrently on 8/7/00 (~ 5 months following collection)**

Animal ID	Time Point	Avg. DPM's/g found from solubilization done concurrently with extraction	Avg. DPM's/g found from extraction	% Recovery	% Avg. Recovery For Timepoint
12-Hour Toluene Extracted Feces					
C8421	12-hr	2894319	1636016	57	31
C8422	12-hr	3522034	1575317	45	
C8423	12-hr	Not enough sample remaining for analysis			
C8424	12-hr	4299474	1108032	26	
C8427	12-hr	2629325	310738	12	
C8428	12-hr	4542362	1086456	24	
C8429	12-hr	3930450	1299604	33	
C8430	12-hr	675749	144557	21	
24-Hour Toluene Extracted Feces					
C8421	24-hr	5552707	2816443	51	43
C8422	24-hr	3568235	1521461	43	
C8423	24-hr	6965786	3547250	51	
C8424	24-hr	2605425	960845	37	
C8427	24-hr	5486894	2146492	39	
C8428	24-hr	4740681	1989137	42	
C8429	24-hr	3645123	2015688	55	
C8430	24-hr	4290316	1293691	30	
48-Hour Toluene Extracted Feces					
C8421	48-hr	356954	143195	40	30
C8422	48-hr	131349	24569	19	
C8423	48-hr	417789	198296	47	
C8424	48-hr	89437	44126	49	
C8427	48-hr	457411	97914	21	
C8428	48-hr	286296	35722	12	
C8429	48-hr	83245	28875	35	
C8430	48-hr	228630	32602	14	

**Table 5. Stability Analysis: Comparison of Solubilizations and Analyses After Initial Analysis and After Storage done 8/7/00 (~ 5 months following collection)**

Animal ID	Time Point	Avg. DPM's/g found from solubilization done originally	Avg. DPM's/g found from solubilization after storage	% Recovery	% Avg. Recovery For Timepoint
<b>12-Hour Solubilized Feces</b>					
C8421	12-hr	3390019	2894319	85	95
C8422	12-hr	2982693	3522034	118	
C8423	12-hr	799785	Not enough sample remaining for analysis		
C8424	12-hr	4148561	4299474	104	
C8427	12-hr	3036609	2629325	87	
C8428	12-hr	4509974	4542362	101	
C8429	12-hr	4474675	3930450	88	
C8430	12-hr	827921	675749	82	
<b>24-Hour Solubilized Feces</b>					
C8421	24-hr	5822632	5552707	95	101
C8422	24-hr	3460076	3568235	103	
C8423	24-hr	6346882	6965786	110	
C8424	24-hr	2671982	2605425	98	
C8427	24-hr	6309211	5486894	87	
C8428	24-hr	4278045	4740681	111	
C8429	24-hr	3548588	3645123	103	
C8430	24-hr	4247633	4290316	101	
<b>48-Hour Solubilized Feces</b>					
C8421	48-hr	378824	356954	94	105
C8422	48-hr	96260	131349	136	
C8423	48-hr	431253	417789	97	
C8424	48-hr	89762	89437	100	
C8427	48-hr	475761	457411	96	
C8428	48-hr	259009	286296	111	
C8429	48-hr	81744	83245	102	
C8430	48-hr	223590	228630	102	
<b>Average of all =</b>					<b>100</b>

**Table 6. Spiking Experiment: Extraction Recovery Results for Homogenized Feces Samples (Spiked After Homogenization) and Non-Homogenized Feces Samples (Homogenized 1 Day After Spiking) After 1 Day of Frozen Storage**

Sample ID	Avg. DPM's/g found from solubilization	Avg. DPM's/g found from extraction	% Recovery	% Avg. Recovery For Level
<b>Homogenized Feces Samples (Spiked After Homogenization)</b>				
Blank 1-HOM	174	2127		
Blank 2-HOM	132	2217		
Blank 3-HOM	171	1937		
Spike A-1-HOM	2369126	2481592	105	108
Spike A-2-HOM	2424086	3432373	142	
Spike A-3-HOM	2927358	2299338	79	
Spike B-1-HOM	3701558	4157822	112	76
Spike B-2-HOM	10049672	4895983	49	
Spike B-3-HOM	6114122	4019993	66	
<b>Average of both levels =</b>				<b>92</b>
<b>Non-Homogenized Feces Samples (Homogenized after Spiking)</b>				
Blank 1-NON	113	1756		
Blank 2-NON	108	1732		
Blank 3-NON	118	1760		
Spike A-1-NON	791201	633207	80	81
Spike A-2-NON	739606	629251	85	
Spike A-3-NON	780374	605479	78	
Spike B-1-NON	1281280	1139051	89	88
Spike B-2-NON	1289873	1130867	88	
Spike B-3-NON	1279340	1115932	87	
<b>Average of both levels =</b>				<b>84</b>

**Table 7. Spiking Experiment: Extraction Recovery Results for Homogenized Feces Samples (Spiked After Homogenization) and Non-Homogenized Feces Samples (Homogenized 1 Day After Spiking) After 30 Days of Frozen Storage**

Sample ID	Avg. DPM's/g found from solubilization	Avg. DPM's/g found from extraction	% Recovery	% Avg. Recovery For Level
<b>Homogenized Feces Samples (Spiked After Homogenization)</b>				
Blank 1-HOM	133	2343		
Blank 2-HOM	133	2223		
Blank 3-HOM	134	1989		
Spike A-1-HOM	2609406	3530569	135	106
Spike A-2-HOM	2530738	2076846	82	
Spike A-3-HOM	2263887	2311849	102	
Spike B-1-HOM	6375996	3087703	48	73
Spike B-2-HOM	4304158	3964176	92	
Spike B-3-HOM	3946319	3128189	79	
Average of both levels =				90
<b>Non-Homogenized Feces Samples (Homogenized after Spiking)</b>				
Blank 1-NON	142	2343		
Blank 2-NON	133	1914		
Blank 3-NON	121	1802		
Spike A-1-NON	732256	309826	42	44
Spike A-2-NON	745617	330733	44	
Spike A-3-NON	749244	342738	46	
Spike B-1-NON	1237402	536107	43	43
Spike B-2-NON	1271085	513975	40	
Spike B-3-NON	1234887	567235	46	
Average of both levels =				44

**Table 8. Spiking Experiment: Solubilization Recovery Results for Homogenized Feces Samples (Spiked After Homogenization) and Non-Homogenized Feces Samples (Homogenized 1 Day After Spiking) After 1 Day and 30 Days of Frozen Storage**

Sample ID	DPM's/g Spiked	Avg. DPM's/g found from solubilization after 1 Day	% Recovery after 1 Day	% Avg. Recovery after 1 Day For Level	Avg. DPM's/g found from solubilization after 30 Days	% Recovery after 30 Days	% Avg. Recovery after 30 Days For Level
Homogenized Feces Samples (Spiked After Homogenization)							
Blank 1-HOM	0	174			133		
Blank 2-HOM		132			133		
Blank 3-HOM		171			134		
Spike A-1-HOM	3047541	2369126	78	84	2609406	86	81
Spike A-2-HOM		2424086	80		2530738	83	
Spike A-3-HOM		2927358	96		2263887	74	
Spike B-1-HOM	5327567	3701558	69	124	6375996	120	92
Spike B-2-HOM		10049672	189		4304158	81	
Spike B-3-HOM		6114122	115		3946319	74	
Average of both levels =				104	Average of both levels =		86
Non-Homogenized Feces Samples (Homogenized after Spiking)							
Blank 1-NON		113			142		
Blank 2-NON		108			133		
Blank 3-NON		118			121		
Spike A-1-NON	828561	791201	95	93	732256	88	90
Spike A-2-NON		739606	89		745617	90	
Spike A-3-NON		780374	94		749244	90	
Spike B-1-NON	1398384	1281280	92	92	1237402	88	89
Spike B-2-NON		1289873	92		1271085	91	
Spike B-3-NON		1279340	91		1234887	88	
Average of both levels =				92	Average of both levels =		89

Table 9. Extraction Efficiency Results from the Extraction of Study 12-hr, 24-hr, and 48-hr Feces Samples from Part 3 with Toluene and Tetrahydrofuran (THF)

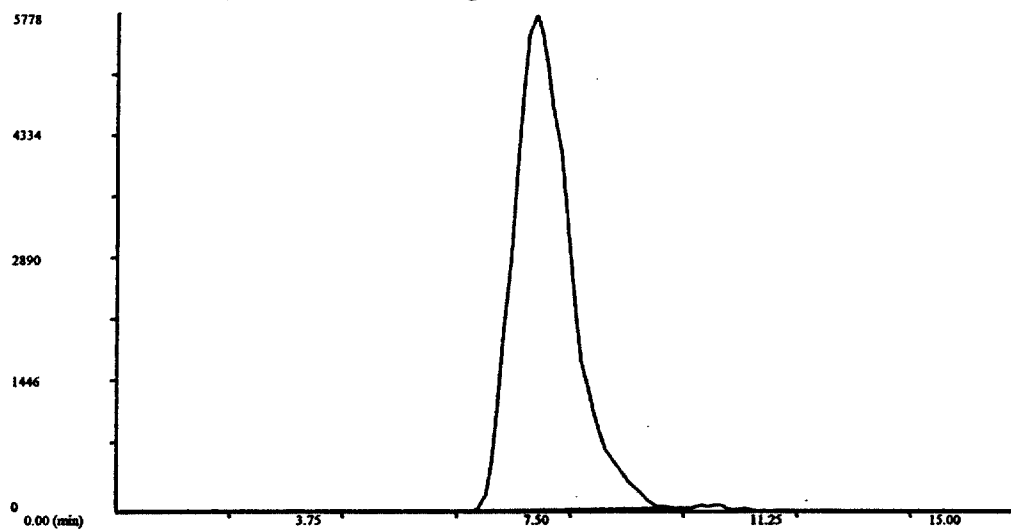
Animal ID	Time Point	Avg. DPM's/g found from extraction with Toluene	Avg. DPM's/g found from solubilization	% Extracted in Toluene vs. Solubilized	Avg. DPM's/g found from subsequent extraction with THF after toluene extraction	% Extracted in THF vs. Solubilized	Combined % Extracted in Toluene and THF vs. Solubilized	DPM's/g found from solubilization of extracted fecal homogenate pellet remaining after extractions	% Left in fecal homogenate as unextracted vs. solubilized of original sample
C9230	12-hr	1990910	2270901	87.7	261153	11.5	99.2	46764	2.1
C9232	12-hr	2657225	2922228	90.9	141673	4.8	95.8	9014	0.3
C9238	12-hr	1016287	1199244	84.7	213056	17.8	102.5	12818	1.1
C9239	12-hr	1268	2593	N/AP <sup>a</sup>	188	N/AP <sup>a</sup>	N/AP <sup>a</sup>	912	N/AP <sup>a</sup>
C9230	24-hr	4191526	5719188	73.3	976928	17.1	90.4	34112	0.6
C9232	24-hr	3240245	4265658	76.0	620039	14.5	90.5	38156	0.9
C9238	24-hr	4585369	6216988	73.8	1230915	19.8	93.6	38801	0.6
C9239	24-hr	3696482	5317172	69.5	938626	17.7	87.2	50394	0.9
C9230	48-hr	606611	789688	76.8	84870	10.7	87.6	1399	0.2
C9232	48-hr	363351	487924	74.5	59489	12.2	86.7	2541	0.5
C9238	48-hr	782468	1094462	71.5	180914	16.5	88.0	11215	1.0
C9239	48-hr	574223	783933	73.2	112336	14.3	87.6	4745	0.6
Average Percentages for all timepoints =				77.4		14.3	91.7		0.8

N/AP<sup>a</sup> = amount of radioactivity in this sample was too low for extraction and quantitation

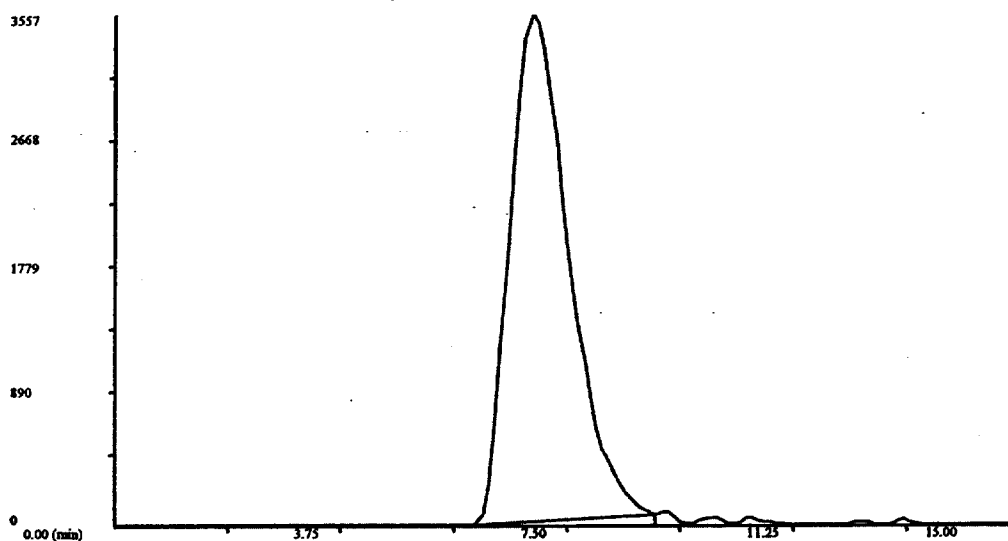
**Table 10. Extraction Efficiency Results from the Extraction of Quality Control (QC) Feces Samples from Part 3 with Toluene and Tetrahydrofuran (THF)**

Sample ID	Time Point	Avg. DPM's/g spiked	Avg. DPM's/g found from extraction	% Recovery	% Avg. Recovery For Timepoint
12-Hour Toluene Extracted Feces QC Samples					
Blank	12-hr	0	0		
Spike A	12-hr	16303	14746	90	94
Spike B	12-hr	625081	595429	95	
Spike C	12-hr	1432056	1388591	97	
24-Hour Toluene Extracted Feces QC Samples					
Blank	24-hr	0	0		
Spike A	24-hr	17715	14707	83	90
Spike B	24-hr	612610	564421	92	
Spike C	24-hr	1356933	1286657	95	
48-Hour Toluene Extracted Feces QC Samples					
Blank	48-hr	0	0		
Spike A	48-hr	13592	14713	108	99
Spike B	48-hr	605416	575049	95	
Spike C	48-hr	1439133	1342000	93	
Average of all toluene QC Samples =					94
THF Extracted Feces QC Samples					
Blank		0	0		
Spike A		13490	11707	87	89
Spike B		549987	482036	88	
Spike C		1269638	1177458	93	

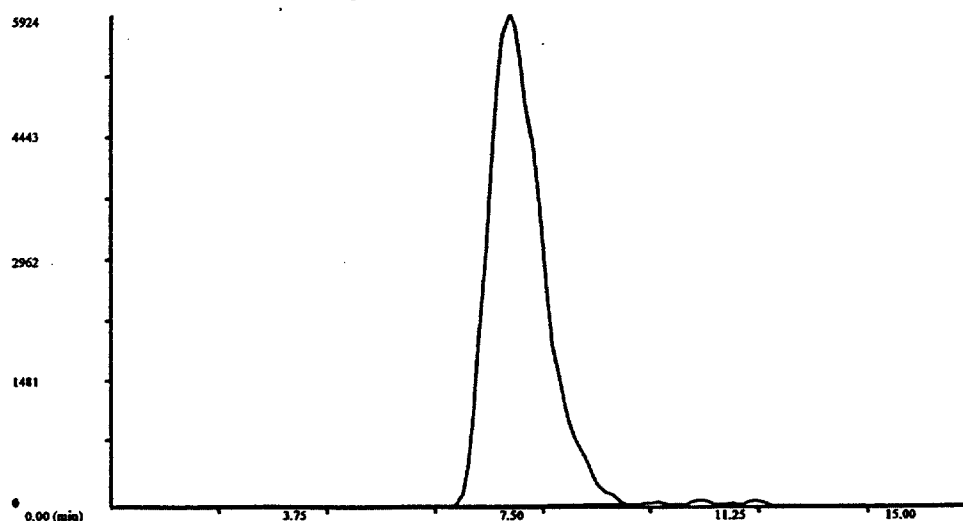
Figure 1. Example Radio-Chromatograms of THF Extracts of Fecal Homogenates



GPC Radio-Chromatogram of a 12-hr Male Rat Fecal THF Extract

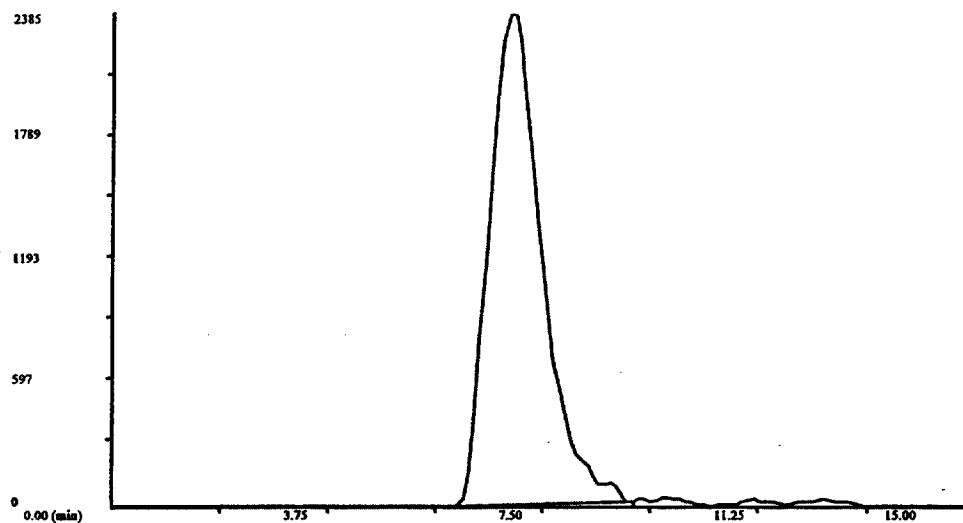


GPC Radio-Chromatogram of a 12-hr Female Rat Fecal THF Extract

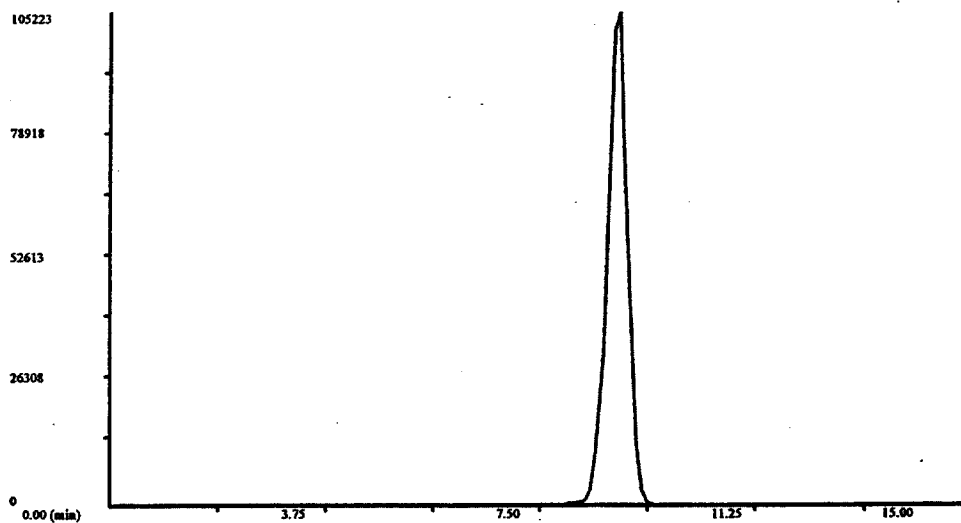


GPC Radio-Chromatogram of a  $^{14}\text{C}$ -PDMS, 350 cSt, Spiked Control Fecal THF Extract

Figure 2. Example Radio-Chromatograms of THF Solvent Standards of  $^{14}\text{C}$ -PDMS, 350cSt and  $^{14}\text{C}$ -D<sub>4</sub>

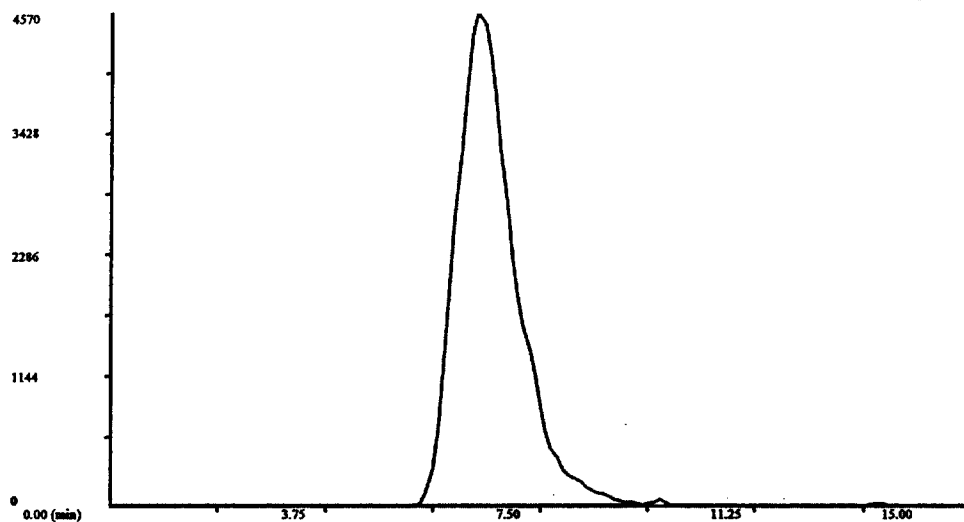


GPC Radio-Chromatogram of a  $^{14}\text{C}$ -PDMS, 350 cSt THF Solvent Standard

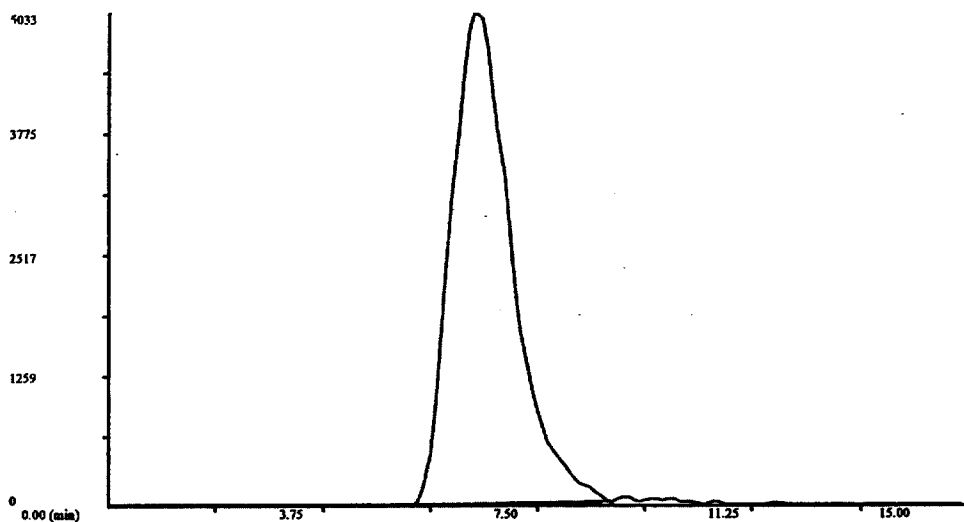


GPC Radio-Chromatogram of a  $^{14}\text{C}$ -D<sub>4</sub> THF Solvent Standard

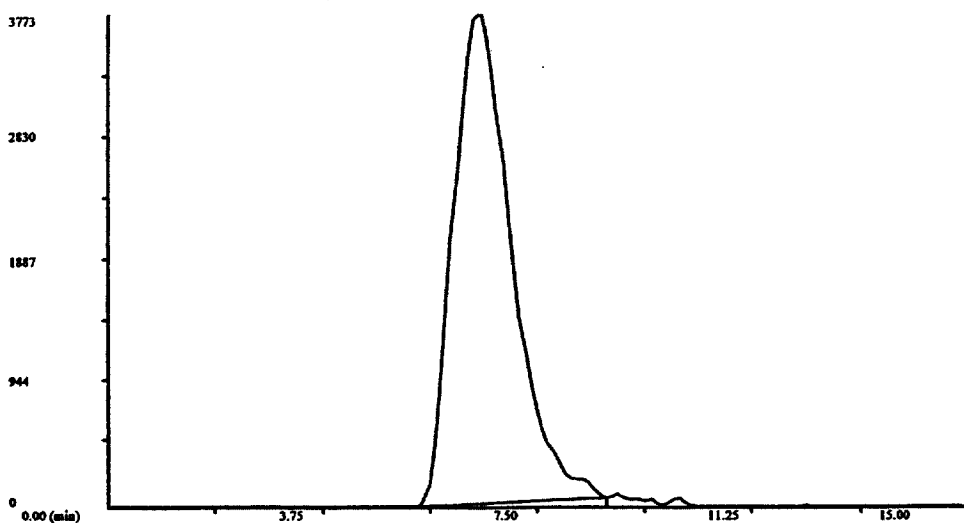
Figure 3. Example Radio-Chromatograms of Toluene Extracts of Fecal Homogenates



GPC Radio-Chromatogram of a 12-hr Male Rat Fecal Toluene Extract



GPC Radio-Chromatogram of a 12-hr Female Rat Fecal Toluene Extract



GPC Radio-Chromatogram of a  $^{14}\text{C}$ -PDMS, 350 cSt, Spiked Control Fecal THF Extract



## **ATTACHMENT A**

### **Tetrahydrofuran Extraction and Analysis of Feces Collected from Animals Dosed By Oral Gavage 1000mg/kg $^{14}\text{C}$ -PDMS**

#### **Individual Results and Example Calculations**

## EXAMPLE CALCULATIONS

### HPLC System Recovery

$$\% \text{ System Recovery} = \frac{\text{HPLC CPM detected} / \mu\text{L injected}}{\text{Ave. LSC CPM detected} / \mu\text{L counted}} \times 100$$

### Feces QC Spikes

#### Spiking Standard Solution Calculations

$$[\text{PDMS}] \text{ mg/g Stock A} = \text{weight of Std or Stock Added (g)} / \text{Total Soln. Weight (g)} \times 1000 \text{ mg/g}$$

$$[\text{PDMS}] \text{ mg/g Stock B} = \text{weight of Std or Stock Added (g)} \times [\text{PDMS}] \text{ mg/g of stock} / \text{Total Soln. Weight (g)}$$

$$\text{uCi/g solvent Stock A} = \text{weight of Std or Stock Added (g)} \times \text{Specific Activity of } ^{14}\text{C-PDMS (mCi/g)} /$$

$$\text{Total Soln. Weight (g)} \times 1000 \text{ uCi/mCi}$$

$$\text{uCi/g solvent Stock B} = \text{weight of Std or Stock Added (g)} \times \text{uCi/g solvent of stock} / \text{Total Soln. Weight (g)}$$

$$\text{dpm/g} = \text{uCi/g solvent} \times 2.22 \times 10^6 \text{ dpm/uCi}$$

#### QC Spike Calculations

$$\text{Weight of Extractant} = \text{Tare Weight} + \text{Extractant (g)} - \text{Weight. Of empty Extractant vial (g)}$$

$$\text{ug PDMS added in spike} = \text{Weight of spike added (g)} \times [\text{PDMS}] \text{ mg/g (for applicable standard)} \times 1000 \text{ ug/mg}$$

$$\text{uCi PDMS spiked} = \text{Weight of spike added (g)} \times \text{dpm/g (for applicable standard)} \times 1 \text{ uCi} / 2.22 \times 10^6 \text{ dpm}$$

$$\text{uCi PDMS/g solvent spiked} = \text{uCi PDMS spiked} / \text{Weight of extractant (g)}$$

dpm PDMS/g solvent spiked = uCi PDMS/g solvent spiked x  $2.22 \times 10^6$  dpm/uCi

#### QC Spike Results

dpm theo = LSC aliquot weights 1,2 (g) x dpm PDMS/g solvent spiked

dpm - blank = dpm actual - average of dpm actual in blanks

% Recovery (for dpm) = dpm-blank / dpm theo x 100

dpm/g found = dpm blank / LSC aliquot weights 1,2 (g)

Average % Recovery (for dpm/g) = dpm/g found / dpm PDMS/g solvent spiked x 100

#### Sample Results

Aliquot Weight of Feces Homogenate Extracted (g) = Tare weight + aliquot of feces homogenate (g) - Tare weight of sample Vial (g)

Weight of solvent extractant (g) = Tare + extractant weight (g) - weight of empty extractant vial weight (g)

dpm/g feces homogenate found from extraction = dpm found from extractant / LSC aliquot weight (g) x wt. of extractant (g)

Aliquot weight of feces homogenate extracted (g)

% Recovery = Average dpm/g / Ave. dpm/g found from solubilization x 100

## 12 Hour Feces - THF Extraction on 3/28/00

Sample ID	actual Injected	LSC (~300ul) CPM	Average LSC CPM's	HPLC (~100ul) CPM detected at ~ 6.9 min	% System Recovery
		detected			
C8421-1	100	122470.00	118974.50	40221.00	101
C8421-2	100	115479.00			
C8422-1	100	125022.00	120108.50	46860.00	117
C8422-2	100	115195.00			
C8423-1	100	21920.60	21969.55	6901.00	94
C8423-2	100	22018.50			
C8424-1	100	147323.00	143228.00	54016.00	113
C8424-2	100	139133.00			
C8427-1	100	105069.00	75711.30	41639.00	165
C8427-2	100	46353.6			
C8428-1	100	143563.00	150011.50	63353.00	127
C8428-2	100	156460.00			
C8429-1	100	138660.00	141520.00	54196.00	115
C8429-2	100	144380.00			
C8430-1	100	29279.80	29109.70	9644.00	99
C8430-2	100	28939.60			
					116

## 24 Hour Feces - THF Extraction on 3/28/00

Sample ID	actual Injected	LSC (~300ul) CPM	Average LSC CPM's	HPLC (~100ul) CPM detected at ~ 6.9 min	% System Recovery
		detected			
C8421-1	100	168502.00	165433.00	64196.00	116
C8421-2	100	162364.00			
C8422-1	100	126615.00	121124.00	47483.00	118
C8422-2	100	115633.00			
C8423-1	100	241369.00	242168.50	92642.00	115
C8423-2	100	242968.00			
C8424-1	100	84954.00	84353.95	29738.00	106
C8424-2	100	83753.90			
C8427-1	100	218514.00	208090.50	82228.00	119
C8427-2	100	197667.00			
C8428-1	100	153208.00	151953.00	59655.00	118
C8428-2	100	150698.00			
C8429-1	100	127524.00	124472.50	53264.00	128
C8429-2	100	121421.00			
C8430-1	100	137095.00	140205.50	52862.00	113
C8430-2	100	143316.00			
					117



48 Hour Feces - THF Extraction on 3/28/00

Sample ID	actual injected	LSC (~300ul) CPM detected	Average LSC CPM's	HPLC (~100ul) CPM detected at ~ 6.9 min	% System Recovery
C8421-1	100	12256.80	12244.70	3230.00	79
C8421-2	100	12232.60			
C8422-1	100	3162.96	3149.35	BLQ	
C8422-2	100	3135.74			
C8423-1	100	15935.60	15929.15	5620.00	106
C8423-2	100	15922.70			
C8424-1	100	3215.11	3147.76	BLQ	
C8424-2	100	3080.40			
C8427-1	100	16226.10	16427.45	5510.00	101
C8427-2	100	16628.80			
C8428-1	100	8371.72	8224.43	3323.00	121
C8428-2	100	8077.14			
C8429-1	100	2434.50	2388.61	BLQ	
C8429-2	100	2342.71			
C8430-1	100	7164.81	7378.92	2131.00	87
C8430-2	100	7593.03			99

BLQ = below quantitation limit of HPLC Detector



Feces QC Spikes

Spiking Standard Solution Calculations

Specific activity of 14C-PDMS, 350 cSt 0.26 mCi/g

Standard	Standard/Stock Added ID	Weight of Standard or stock added (g)	Total Soln. Weight (g)	[PDMS] mg/g	uCi/g THF	dpm/g	Lot #
QC STK A	14C-PDMS	0.0736	0.9761	75.402	19.32	42887367	00C0080
QC STK B	QC STK A	0.0850	0.8866	7.229	1.85	4111692	00C0081

QC Spike Calculations

Feces	Spiked Stock Added ID	Weight of Spike Added (g)	Weight of empty extractant vial (g)	Tare Weight + Extractant (g)	Weight of extractant (g)	ug PDMS added in spike	uCi PDMS spiked	dpm PDMS/g THF spiked
Blank	none	0.0000	5.6364	6.9609	1.3245	0.00	0.00	0
Spike A	QC STK B	0.0032	5.6770	7.0357	1.3587	23.13	0.01	9684
Spike B	QC STK A	0.0110	5.6082	6.9406	1.3324	829.42	0.21	354069
Spike C	QC STK A	0.0252	5.6459	7.0254	1.3795	1900.13	0.49	783444

QC Spike Results

Feces	dpm PDMS/g THF spiked	LSC Aliquot weights 1,2 (g)	dpm theo	dpm actual	dpm - blank	% Recovery	average % Recovery of 2 aliquots	dpm/g found	Ave dpm/g found	Average % Recovery
Blank	0	0.2695	0	20.08	0			0	0	
Spike A	9684	0.2662	0	19.52	0			0		
		0.2655	2571	1937.43	1918	75	73	7223	7109	73
Spike B	354069	0.2727	2641	1927.15	1907	72	84	6994		
		0.2658	94111	78812.8	78793	84	84	296437	296090	84
		0.2675	94713	79130.8	79111	84		295742		
Spike C	783444	0.2700	211530	167984	167964	79	78	622090	614390	78
		0.2665	208788	161703	161683	77	78	606691		
										78

Animal ID	Time Point	Avg. DPM's/g found from solubilization	Tare weight of Sample vial (g)	Tare weight of Aliquot of feces homogenate (g)	Weight of empty extractant vial (g)	Tare + extractant weight (g)	Weight of THF extractant (g)	LSC aliquot weight (g)	dpm found from extractant	dpm/g feces homogenate found from extraction	Average of duplicate (dpm/g)	% Recovery	% Ave Recovery For Timepoint
C8421	12hr	3390019	4.9727	5.2088	0.2361	5.6417	1.1898	0.2735	129734	2380421	2320117	68	77
C8422	12hr	2982883	4.9828	5.2237	0.2309	5.6173	1.2318	0.2740	122328	2249812	2430921	82	
C8423	12hr	799785	4.9593	5.1268	0.1875	5.6556	1.2970	0.2785	121836	2350998	2430921	82	
C8424	12hr	4148561	4.9858	5.2001	0.2143	5.6821	1.2980	0.2728	23259.6	680211	658305	82	
C8427	12hr	3038809	5.0211	5.2408	0.2195	5.6762	1.2977	0.2697	147211	3308088	3385183	82	
C8428	12hr	4509974	4.9633	5.1790	0.2157	5.6773	1.3318	0.2719	152073	3453280	3596152	80	
C8429	12hr	4474675	4.9889	5.2127	0.2238	5.6474	1.3412	0.2712	148433	3235808	3287609	74	
C8430	12hr	827921	4.9990	5.2415	0.2425	5.6342	1.4156	0.2721	152531	3359410	648594	78	
C8421	24hr	5822832	5.0274	5.1909	0.1635	5.6504	1.3003	0.2663	178035	5318919	5241812	90	85
C8422	24hr	3460076	4.9339	5.1563	0.2224	5.6397	1.3573	0.2637	171316	5168704	2913788	84	
C8423	24hr	6346882	4.9808	5.2151	0.2345	5.6498	1.3522	0.2653	122288	2813118	3014420	88	
C8424	24hr	2871982	5.0184	5.2265	0.2071	5.6541	1.3369	0.2675	257355	5425920	5456971	81	
C8427	24hr	6309211	4.9578	5.1696	0.2118	5.6476	1.3337	0.2687	88850.4	2145737	2158175	83	
C8428	24hr	4278045	4.9472	5.1689	0.2217	5.5098	1.3354	0.2681	209785	4827309	5229793	85	
C8429	24hr	3546588	4.9657	5.2035	0.2378	5.6088	1.3467	0.2687	182545	3676615	3630806	79	
C8430	24hr	4247633	4.9419	5.1259	0.1840	5.6726	1.3203	0.2654	129916	2750837	2791073	94	
C8421	48hr	378824	5.0052	5.2365	0.2333	5.6100	1.2729	0.2653	151761	4104665	3990825	70	73
C8422	48hr	96280	4.9831	5.2168	0.2337	5.6294	1.3656	0.2682	12937.6	285171	264870	75	
C8423	48hr	431253	5.0311	5.2754	0.2443	5.6997	1.3397	0.2670	3297.53	72178	72579	78	
C8424	48hr	89762	4.9780	5.2262	0.2532	5.5941	1.3643	0.2711	18901.9	334692	338292	74	
C8427	48hr	475761	4.9899	5.2311	0.2412	5.6640	1.3239	0.2703	3288.1	65147	68005	74	
								0.2716	17247.3	348553	352008	74	
								0.2730	17679.9	355464			



Animal ID	Time Point	Avg. DPM's/g found from solubilization	Tare weight of Sample vial (g)	Tare weight + Aliquot of feces homogenate (g)	Allquot Weight of feces homogenate extracted (g)	Weight of empty extractant vial (g)	Tare + extractant weight (g)	Weight of THF extractant (g)	LSC aliquot weight (g)	dpm found from extractant	dpm/g feces homogenate found from extraction	Average of duplicate (dpm/g)	% Recovery	% Ave Recovery For Timepoint
C8428	48hr	259009	4.9597	5.1977	0.2390	5.8146	6.9527	1.3381	0.2718	8890.82	183909	181853	70	
C8429	48hr	81744	5.0321	5.2787	0.2486	5.6390	7.0028	1.3838	0.2680	8570.44	179786	52470	64	
C8430	48hr	223590	4.9728	5.2024	0.2296	5.8095	6.9508	1.3411	0.2661	2581.58	51593	167887	75	
									0.2728	2482.43	162891	172883		
									0.2720	7602.12	8050.67			

## **ATTACHMENT B**

### **Toluene Extraction and Analysis of Feces Collected from Animals Dosed By Oral Gavage 1000mg/kg $^{14}\text{C}$ -PDMS**

#### **Individual Results and Example Calculations**

## EXAMPLE CALCULATIONS

### Method Development Feces QC's

#### Spiking Standard Solution Calculations

$[\text{PDMS}] \text{ mg/g Stock A} = \text{weight of Std or Stock Added (g)} / \text{Total Soln. Weight (g)} \times 1000 \text{ mg/g}$

$[\text{PDMS}] \text{ mg/g Stock B} = \text{weight of Std or Stock Added (g)} \times [\text{PDMS}] \text{ mg/g of stock} / \text{Total Soln. Weight (g)}$

$\text{uCi/g solvent Stock A} = \text{weight of Std or Stock Added (g)} \times \text{Specific Activity of } ^{14}\text{C-PDMS (mCi/g)} /$

$\text{Total Soln. Weight (g)} \times 1000 \text{ uCi/mCi}$

$\text{uCi/g solvent Stock B} = \text{weight of Std or Stock Added (g)} \times \text{uCi/g solvent of stock} / \text{Total Soln. Weight (g)}$

$\text{dpm/g} = \text{uCi/g solvent} \times 2.22 \times 10^6 \text{ dpm/uCi}$

#### Samples Extracted in Toluene or THF

$\text{dpm/g of extractant} = \text{Total dpm (extractant)} / \text{LSC} / \text{Wt. of LSC Aliquot (g)}$

$\text{dpm/g (extractant)} \text{ corrected for blanks} = \text{dpm/g of extractant} - \text{average dpm/g of extractant in blanks}$

$\text{Total weight of extractant (g)} = \text{Tare Wt.} + \text{extractant (g)} - \text{Tare Wt. of extractant vial (g)}$

$\text{dpm (pellets)} \text{ corrected for blanks} = \text{Total dpm (pellets)} / \text{LSC} - \text{Average Total dpm (pellets)} / \text{LSC in blanks}$

$\text{Total dpm Ext.} + \text{pellet} = \text{Average Total dpm in Extractant (of 2 aliquots)} + \text{dpm (pellets)} \text{ corrected for blanks}$

Total dpm calculated = Wt. of spike added (g) x dpm/g actual from LSC (for appropriate QC STK used)

% Recovery in Extractant = Duplicates averaged dpm in Extractant / Total dpm calculated x 100

% Recovery in Pellet = dpm (pellets) corrected for blanks / Total dpm calculated x 100

#### **Samples Spiked but Not Extracted**

dpm (pellets) corrected for blanks = Total dpm (pellets) from LSC - Average Total dpm (pellets) from LSC in blanks

Calculated dpm spiked = Wt. of spike added (g) x dpm/g actual from LSC (for appropriate QC STK used)

% Recovery = dpm (pellets) corrected for blanks / Calculated dpm spiked x 100

#### **HPLC System Recovery**

% System Recovery =  $\frac{\text{HPLC CPM detected}}{\text{uL injected}} \times 100$

Ave. LSC CPM detected / uL counted

#### **Feces QC Spikes**

##### **Spiking Standard Solution Calculations**

[PDMS] mg/g Stock A = weight of Std or Stock Added (g) / Total Soln. Weight (g) x 1000 mg/g

[PDMS] mg/g Stock B = weight of Std or Stock Added (g) x [PDMS] mg/g of stock / Total Soln. Weight (g)

$\text{uCi/g solvent Stock A} = \text{weight of Std or Stock Added (g)} \times \text{Specific Activity of } ^{14}\text{C-PDMS (mCi/g)} / \text{Total Soln. Weight (g)} \times 1000 \text{uCi/mCi}$

$\text{uCi/g solvent Stock B} = \text{weight of Std or Stock Added (g)} \times \text{uCi/g solvent of stock} / \text{Total Soln. Weight (g)}$

$\text{dpm/g} = \text{uCi/g solvent} \times 2.22 \times 10^6 \text{ dpm/uCi}$

### QC Spike Calculations

$\text{Weight of Extractant} = \text{Tare Weight} + \text{Extractant (g)} - \text{Weight. Of empty Extractant vial (g)}$

$\text{ug PDMS added in spike} = \text{Weight of spike added (g)} \times [\text{PDMS}] \text{ mg/g (for applicable standard)} \times 1000 \text{ ug/mg}$

$\text{uCi PDMS spiked} = \text{Weight of spike added (g)} \times \text{dpm/g (for applicable standard)} \times 1 \text{uCi} / 2.22 \times 10^6 \text{ dpm}$

$\text{uCi PDMS/g solvent spiked} = \text{uCi PDMS spiked} / \text{Weight of extractant (g)}$

$\text{dpm PDMS/g solvent spiked} = \text{uCi PDMS/g solvent spiked} \times 2.22 \times 10^6 \text{ dpm/uCi}$

### QC Spike Results

$\text{dpm theo} = \text{LSC aliquot weights 1,2 (g)} \times \text{dpm PDMS/g solvent spiked}$

$\text{dpm} - \text{blank} = \text{dpm actual} - \text{average of dpm actual in blanks}$

$\% \text{ Recovery (for dpm)} = \text{dpm-blank} / \text{dpm theo} \times 100$

dpm/g found = dpm blank / LSC aliquot weights 1,2 (g)

Average % Recovery (for dpm/g) = dpm/g found / dpm PDMS/g solvent spiked x 100

### Sample Results

Aliquot Weight of Feces Homogenate Extracted (g) = Tare weight + aliquot of feces homogenate (g) - Tare weight of sample Vial (g)

Weight of solvent extractant (g) = Tare + extractant weight (g) - weight of empty extractant vial weight (g)

dpm/g feces homogenate found from extraction = dpm found from extractant / LSC aliquot weight (g) x wt. of extractant (g)

Aliquot weight of feces homogenate extracted (g)

% Recovery = Average dpm/g / Ave. dpm/g found from solubilization x 100

Spiking Standard Solution Calculations

Specific activity of 14C-PDMS, 350 cS 0.26 mCi/g

Standard	Standard/Stock Added ID	Weight of Standard or stock added (g)	Total Soln. Weight (g)	[PDMS] mg/g	uCi/g THF	dpm/g	Lot #	dpm actual from LSC	wt. of sample analyzed by LSC	dpm/g actual from LSC
QC STK A	14C-PDMS	0.0736	0.9761	75.402	19.32	42887367	00C0080	988614	0.0244	40516967
QC STK B	QC STK A	0.0850	0.8866	7.229	1.85	4111692	00C0081	54093.9	0.0123	4397878



### Samples Extracted in Toluene

	Spike Added	Wt. of Spike Added (g)	Wt. of LSC Aliquot (g)	Total DPM (extractant) from LSC	DPM per g of Extractant	DPM/g (extractant) corrected for Blanks	Tare Wt. Of Extractant Vial (g)	Tare Wt. + Extractant (g)	Total wt. of Extractant (g)	Total DPM in Extractant	Duplicates Averaged DPM in Extractant	Total DPM (pellets) from corrected for LSC	Total DPM (pellets) Ext. + Pellet	Total DPM Calculated	% Recovery in Extractant	% Recovery in Pellet
Blank 1		0.0000	0.1322	14.96	113		5.7856	6.9849	1.2093			28.43				
			0.1325	20.09	152											
Blank 2		0.0000	0.1338	17.48	131		5.7115	6.9257	1.2142			27.68				
			0.1358	14.45	106											
Spike A1	QC-STK-B	0.0032	0.1346	1395.57	10368	10243	5.7373	6.8793	1.1420	11697	11609	1553.52	13134	14073	82.49	10.84
			0.1337	1365.54	10213	10088				11521						
Spike A2	QC-STK-B	0.0031	0.1327	1317.00	9925	9799	5.7170	6.9051	1.1881	11642	11661	1116.11	12749	13633	85.53	7.98
			0.1333	1327.20	9958	9831				11880						
Spike B1	QC-STK-A	0.0111	0.1346	52007.0	386382	387107	5.6639	6.8440	1.1801	455821	456323	8466.94	464762	449738	101.46	1.88
			0.1341	51927.9	387233	397397				456825						
Spike B2	QC-STK-A	0.0110	0.1345	53466.8	397523	397397	5.7427	6.9133	1.1706	485193	485795	8562.04	474329	445687	104.51	1.91
			0.1341	53445.7	396551	396426				486397						
Spike C1	QC-STK-A	0.0244	0.1344	112842	839598	839473	5.7036	6.9005	1.1969	1004765	1005068	13929.0	1018969	988614	101.66	1.41
			0.1338	112238	840105	839979				1005371						
Spike C2	QC-STK-A	0.0232	0.1344	111821	832001	831876	5.7157	6.8870	1.1513	957739	964438	12865.6	977395	939994	102.60	1.38
			0.1333	112457	843638	843513				971136						

### Samples Extracted in THF

	Spike Added	Wt. of Spike Added (g)	Wt. of LSC Aliquot (g)	Total DPM (extractant) from LSC	DPM per g of Extractant	DPM/g (extractant) corrected for Blanks	Tare Wt. Of Extractant Vial (g)	Tare Wt. + Extractant (g)	Total wt. of Extractant (g)	Total DPM in Extractant	Duplicates Averaged DPM in Extractant	Total DPM (pellets) from corrected for LSC	Total DPM (pellets) Ext. + Pellet	Total DPM Calculated	% Recovery in Extractant	% Recovery in Pellet
Blank 3		0.0000	0.1420	16.17	126		5.6872	6.8736	1.1864			31.85				
			0.1434	19.77	138											
Blank 4		0.0000	0.1431	17.98	126		5.7237	6.9433	1.2196			28.90				
			0.1428	16.80	116											
Spike A3	QC-STK-B	0.0036	0.1428	1304.36	9134	9007	5.7271	6.8479	1.1208	10095	10094	2635.02	12700	15832	63.76	16.46
			0.1440	1315.06	9132	9005				10093						
Spike A4	QC-STK-B	0.0035	0.1429	1320.09	9238	9111	5.7349	6.8320	1.0971	9998	9922	2816.35	12709	15393	64.46	18.11
			0.1431	1302.64	9103	8976				9848						
Spike B3	QC-STK-A	0.0114	0.1439	48167.5	334729	334602	5.7331	6.9820	1.2489	417884	419785	20992.3	440748	461893	90.88	4.54
			0.1440	48639.3	337773	337646				421686						
Spike B4	QC-STK-A	0.0109	0.1440	47343.4	328774	328647	5.7716	6.9354	1.1638	382479	380841	43206.5	423818	441635	86.19	9.78
			0.1430	46563.0	325815	325488				378803						
Spike C3	QC-STK-A	0.0249	0.1431	108615	758015	758888	5.6773	6.8976	1.2203	928071	918808	54424.8	973204	1008872	91.07	5.39
			0.1441	107659	747113	746986				911547						
Spike C4	QC-STK-A	0.0239	0.1431	113854	796324	796197	5.6965	6.8583	1.1618	925022	920527	33908.1	954406	968356	95.06	3.50
			0.1429	112689	789586	789459				916032						

# Samples Spiked but Not Extracted

	Spike Added	Wt. of Spike Added (g)	Total DPM (pellets) from LSC	DPM (pellets) corrected for blanks	Calculated DPM Spiked	% Recovery
Blank 5		0.0000	27.86		0	
Blank 6		0.0000	29.91		0	
Spike A5	QC STK B	0.0034	15410.4	15352	14953	102.87
Spike A6	QC STK B	0.0035	15227.0	15198	15393	98.74
Spike B5	QC STK A	0.0110	483031	483002	445687	103.89
Spike B6	QC STK A	0.0109	484020	483991	441635	105.08
Spike C5	QC STK A	0.0247	1081200	1081171	1000769	106.04
Spike C6	QC STK A	0.0244	1032649	1032620	988614	104.47
						103.51

### 12 Hour Feces - Toluene Extraction on 6/14/00

Sample ID	actual injected	LSC (~50ul)	Average	HPLC (~100ul)	% System Recovery
		CPM detected	LSC CPM's	CPM detected at ~ 6.5 min	
C8421-1	100	28504.00	28291.15	61902.00	109
C8421-2	100	28078.30			
C8422-1	100	12998.70	13058.70	27358.00	105
C8422-2	100	13118.70			
C8423-1	100	3688.64	3855.49	7809.00	101
C8423-2	100	4022.34			
C8424-1	100	16051.50	16141.30	33426.00	104
C8424-2	100	16231.10			
C8427-1	100	19739.20	18973.50	40377.00	106
C8427-2	100	18207.8			
C8428-1	100	24281.60	24173.15	54504.00	113
C8428-2	100	24064.70			
C8429-1	100	21694.30	22307.70	47702.00	107
C8429-2	100	22921.10			
C8430-1	100	5411.59	5435.64	10734.00	99
C8430-2	100	5459.69			
					105

### 24 Hour Feces - Toluene Extraction on 6/14/00

Sample ID	actual injected	LSC (~50ul)		HPLC (~100ul)	% System Recovery
		CPM detected	Average LSC CPM's	CPM	
				detected at ~ 6.5 min	
C8421-1	100	47077.20	46847.70	96870.00	103
C8421-2	100	46618.20			
C8422-1	100	22486.70	22164.25	48382.00	109
C8422-2	100	21841.80			
C8423-1	100	37662.20	38405.15	82206.00	107
C8423-2	100	39148.10			
C8424-1	100	15402.00	15331.50	29912.00	98
C8424-2	100	15261.00			
C8427-1	100	32988.90	32919.20	73611.00	112
C8427-2	100	32849.50			
C8428-1	100	18184.80	18197.85	38570.00	106
C8428-2	100	18210.90			
C8429-1	100	12927.00	12926.50	25598.00	99
C8429-2	100	12926.00			
C8430-1	100	28690.80	28419.85	65092.00	115
C8430-2	100	28148.90			
					106

### 48 Hour Feces - Toluene Extraction on 6/14/00

Sample ID	actual injected	LSC (~50ul) CPM detected	Average LSC CPM's	HPLC (~100ul) CPM detected at ~ 6.5 min	% System Recovery
C8421-1	100	2983.28	2904.56	5332.00	92
C8421-2	100	2825.83			
C8422-1	100	683.23	703.46	955.00	68
C8422-2	100	723.68			
C8423-1	100	4244.20	4151.51	8265.00	100
C8423-2	100	4058.82			
C8424-1	100	476.79	491.00	BLQ	
C8424-2	100	505.20			
C8427-1	100	1488.73	1513.00	2038.00	67
C8427-2	100	1537.27			
C8428-1	100	526.97	541.54	BLQ	
C8428-2	100	556.11			
C8429-1	100	496.99	506.45	BLQ	
C8429-2	100	515.91			
C8430-1	100	1341.99	1367.90	BLQ	
C8430-2	100	1393.81			
					82

BLQ = below quantitation limit of HPLC Detector



### Feces QC Spikes

#### Spiking Standard Solution Calculations

Specific activity of 14C-PDMS, 350 cSt 0.26 mCi/g

Standard	Standard/Stock Added ID	Weight of Standard or stock added (g)	Total Soln. Weight (g)	[D4] mg/g	uCi/g THF	dpm/g	Lot #	dpm actual from LSC	wt. of sample analyzed by LSC	dpm/g actual from LSC	Check of specific act. % recovered
QC STK A	14C-PDMS	0.0934	0.9011	103.651	26.56	58954882	00F0179	1016976	0.0173	58784740	100
QC STK B	QC STK A	0.0939	0.9035	10.772	2.76	6127132	00F0180	100537.0	0.0165	6093152	99

### QC Spike Calculations

Feces	Spiked Stock Added ID	Weight of Spike Added (g)	Weight of empty extractant vial (g)	Tare Weight + Extractant (g)	Weight of extractant (g)	ug PDMS added in spike	uCi PDMS spiked	uCi PDMS/toluene spiked	dpm D4/g toluene spiked
Blank	none		5.6576	6.8069	1.1493	0.00	0.00	0.00	0
Spike A	QC STK B	0.0036	5.6360	6.7113	1.0753	38.78	0.01	0.01	20513
Spike B	QC STK A	0.0112	5.6152	6.7698	1.1546	1160.89	0.30	0.26	571882
Spike C	QC STK A	0.0247	5.6653	6.7646	1.0993	2560.18	0.66	0.60	1324648

### QC Spike Results

Feces	dpm D4/g toluene spiked	LSC Aliquot weights 1,2 (g)	dpm theo	dpm actual	dpm - blank	% Recovery	average % Recovery of 2 aliquots	Ave dpm/g found	Average % Recovery
Blank	0	0.0400	0	13.76	-3			0	
		0.0438	0	18.88	3			0	
Spike A	20513	0.0409	839	826.55	810	97	94	19810	19230
		0.0453	929	861.18	845	91		18650	
Spike B	571882	0.0417	23847	22576.8	22560	95	95	541019	541766
		0.0440	25163	23886.9	23871	95		542513	
Spike C	1324648	0.0417	55238	52588.8	52572	95	95	1260731	1260037
		0.0442	58549	55679.3	55663	95	95	1259343	
									95

Animal ID	Time Point	Avg. DPM's/g found from solubilization(Or lignal)	Tare weight of Sample vial (g)	Tare weight of feces homogenate (g)	Aliquot Weight of feces extracted (g)	Weight of empty extractant vial (g)	Tare + extractant weight (g)	Weight of Toluene extractant (g)	LSC aliquot weight (g)	dpm found from extractant	dpm/g feces homogenate found from extraction	Average of duplicate (dpm/g)	% Recovery	Ave % Recovery for Time point
C8421	12hr	3390019	4.9858	5.2839	0.2783	5.8508	6.7647	1.1139	0.0436	30924.6	2839903.287	2827024	83	72
C8422	12hr	2982693	4.9712	5.1316	0.1604	5.6389	6.7935	1.1548	0.0433	30454.8	2815145.545	2329299	78	
C8423	12hr	799785	4.9890	5.3280	0.3370	5.8342	6.8095	1.1753	0.0435	14094.7	232350.248	330950	41	
C8424	12hr	4148561	4.9920	5.1582	0.1642	5.5855	6.8622	1.0787	0.0435	4001.01	320774.0409	2829295	68	
C8427	12hr	3038809	4.9809	5.2620	0.2811	5.8358	6.8131	1.1773	0.0408	17595.3	2841791.448	2037298	67	
C8428	12hr	4509874	5.0010	5.2015	0.2005	5.8386	6.7948	1.1582	0.0434	21410.6	2068166.933	3655997	81	
C8429	12hr	4474875	4.9882	5.1600	0.1718	5.6327	6.7127	1.0800	0.0415	26329.9	3658840.192	3595321	80	
C8430	12hr	827821	4.9723	5.2284	0.2561	5.8489	6.8385	1.1916	0.0412	24854.6	3591849.384	620079	75	
C8421	24hr	5922832	5.0069	5.2051	0.1982	5.5953	6.7329	1.1376	0.0443	5987.82	616302.5817	6548108	112	81
C8422	24hr	3460078	4.9788	5.2068	0.2280	5.8488	6.7882	1.1194	0.0441	51067.1	8557217.752	2783803	80	
C8423	24hr	8348882	5.0464	5.2433	0.1989	5.8010	6.7430	1.1420	0.0434	24378.6	2757842.875	5539934	87	
C8424	24hr	2871982	5.0184	5.2388	0.2184	5.8114	6.7289	1.1455	0.0414	23889.6	2809382.895	1986908	74	
C8427	24hr	8309211	4.9586	5.1933	0.2347	5.6300	6.7128	1.0828	0.0438	40821.7	5430314.531	4036856	64	
C8428	24hr	4278045	4.9778	5.1435	0.1657	5.8421	6.7806	1.1385	0.0408	35828.7	4028567.003	3348558	78	
C8429	24hr	3548588	5.0458	5.2070	0.1612	5.6250	6.7729	1.1479	0.0404	19721.3	3337490.457	2448814	69	
C8430	24hr	4247633	5.0019	5.2421	0.2402	5.6387	6.7621	1.1254	0.0412	35773.3	4045144.118	3510330	83	
C8421	48hr	378824	4.9706	5.3067	0.3361	5.6587	6.7008	1.0439	0.0408	30536.2	3481024.479	230843	61	50
C8422	48hr	96280	5.0128	5.4002	0.3876	5.6117	6.5530	0.9413	0.0409	3235.19	228889.3872	43555	45	
C8423	48hr	431253	4.9125	5.2592	0.3467	5.6749	6.7773	1.1024	0.0442	784.65	43111.98307	337098	78	
C8424	48hr	89762	4.9697	5.2784	0.3087	5.5840	6.6564	1.0724	0.0439	4604.49	333505.021	44246	49	
C8427	48hr	475761	4.9382	5.1572	0.2180	5.6572	6.7388	1.0788	0.0411	4403.7	340891.4748	191908	40	
									0.0407	516.94	44123.0858	44246		
									0.0429	547.92	44369.0408	44246		
									0.0409	1613.64	195384.3278	191908		
									0.0438	1666.53	188427.9867	191908		

Animal ID	Time Point	Avg. DPM's/g found from original	Tare weight of Sample vial (g)	Tare weight of feces homogenate (g)	Allquot Weight of feces extracted (g)	Weight of empty extractant vial (g)	Tare + extractant weight (g)	Weight of Toluene extractant (g)	LSC allquot weight (g)	dpm found from extractant	dpm/g feces homogenate found from extraction	Average of duplicate (dpm/g)	% Recovery	Ave % Recovery for Time point
C8428	48hr	259008	5.0061	5.1842	0.1781	5.6400	6.8717	1.0317	0.0413	571.39	80144.1984	80023	31	
C8429	48hr	81744	5.0012	5.3444	0.3432	5.6463	6.7439	1.0976	0.0415	538.82	79902.37776	41145	50	
C8430	48hr	223590	4.9932	5.3515	0.3583	5.6150	6.8699	1.0549	0.0439	559.8	40787.11747	102322	48	
									0.0441	1454.98	103722.137	100921.9799		
										1511.68				

## **ATTACHMENT C**

**Second Toluene Extraction and Analysis and Solubilization/Analysis  
of Feces Collected from Animals Dosed  
By Oral Gavage 1000mg/kg  $^{14}\text{C}$ -PDMS**

**Individual Results and Example Calculations**



## EXAMPLE CALCULATIONS

### Sample Extracted Results

dpm/g from solubilization = dpm from solubilized feces / wt. of feces solubilized

Aliquot Weight of Feces Homogenate Extracted (g) = Tare weight + aliquot of feces homogenate (g) - Tare weight of sample Vial (g)

Weight of solvent extractant (g) = Tare + extractant weight (g) - weight of empty extractant vial weight (g)

dpm/g feces homogenate found from extraction = dpm found from extractant / LSC aliquot weight (g) x wt. of extractant (g)

Aliquot weight of feces homogenate extracted (g)

% Recovery = Average dpm/g / Ave. dpm/g found from solubilization 080800 x 100

### Sample Solubilized Results

dpm/g from solubilization = dpm from solubilized feces / wt. of feces solubilized

% Recovery solubilization on 8/8/00 compared = avg. dpm's/g found from solubilization on 8/8/00 x 100  
avg. dpm's/g found from solubilization (original)

Animal ID	Time Point	Wt. of feces solubilized (g)	DPM from solubilized feces (g)	DPM/g found from solubilization	Avg. DPM/g found from solubilization	Tare wt of sample vial (g)	Tare wt of aliquot of feces (g)	Aliquot of feces (g)	Weight of empty extractant vial (g)	Tare + extractant vial (g)	Wt of THF extract (g)	LSC aliquot weight (g)	dpm found from extractant	dpm/g feces found from extraction	Average of duplicate (dpm/g)	% Recovery	Ave % Recovery for Timept
C8421	12hr	0.2088	619111	2965091	2964319	3360019	5.0425	0.2127	5.7518	6.7947	1.0428	0.0406	13988	1684913	1638016	57	31
C8422	12hr	0.1931	545227	2823547	3522034	2882363	4.9944	0.1948	5.6757	6.7974	1.1217	0.0406	11092	1573155	1575317	45	
C8423	12hr	0.2159	768804	3551683		769785	5.0178	ns			ns	0.0425	11843	1577480			
C8424	12hr	0.1735	747038	4305695	4289474	4148581	5.0468	0.2000	5.7578	6.8427	1.0849	0.0426	8632	1091475	1108032	26	
C8427	12hr	0.1983	851352	4293253	2629325	3038808	4.9965	0.2140	5.8650	6.8254	0.8804	0.0425	3279	310188	310738	12	
C8428	12hr	0.1908	512787	2988155	4542382	4509874	5.0481	0.2089	5.7020	6.7094	1.0074	0.0416	3213	311279			
C8429	12hr	0.1860	852550	4583802	3930450	4474575	4.9868	0.2128	5.8898	6.8419	1.1521	0.0415	9209	1070109	1088458	24	
C8429	12hr	0.2033	810863	3987521	675749	827821	5.0442	0.2040	5.6732	6.7896	1.1164	0.0420	10155	1297899	1296804	33	
C8430	12hr	0.2021	782810	3873380	675749	827821	5.0442	0.2040	5.6732	6.7896	1.1164	0.0420	10155	1297899	1296804	21	
C8430	12hr	0.2015	152395	716331.8	552707	5822632	4.9951	0.2201	5.8932	6.7268	1.0398	0.0411	1089	148003			
C8421	24hr	0.2713	127866	635166.3	552707	5822632	4.9951	0.2201	5.8932	6.7268	1.0398	0.0411	1089	148003			
C8422	24hr	0.1963	723298	3879023	3688235	3460076	5.0464	0.1837	5.7645	6.8453	1.0808	0.0408	9318	1514886	1521481	43	
C8423	24hr	0.1928	1446094	7508276	8885786	6348882	5.0143	0.1923	5.8512	6.8484	0.9872	0.0408	9398	1627968			
C8424	24hr	0.1842	1183171	6423285	2806425	2671982	5.0417	0.1864	5.7308	6.8244	1.0938	0.0438	28641	3487471	3547250	51	
C8427	24hr	0.2107	1218523	5783213	5488884	6309211	4.9719	0.1957	5.6881	6.7725	1.1044	0.0415	8806	974092	980845	37	
C8428	24hr	0.2084	991029	4755417	4740881	4278045	5.0180	0.1954	5.8831	6.8107	1.1178	0.0412	15852	2150435	2146482	39	
C8429	24hr	0.2081	983469	4725944	3645123	3548588	5.0621	0.1798	5.8463	6.7429	1.0688	0.0434	16016	1078911	1888137	42	
C8430	24hr	0.1942	689448	3447209	4280316	4247633	4.9916	0.1943	5.8571	6.7499	1.0928	0.0435	9905	1290658	1263691	55	
C8421	48hr	0.2218	948748	4288467	359864	378824	5.0684	0.2125	5.8613	6.7325	1.0712	0.0423	1189	138119	143195	30	
C8422	48hr	0.1816	63591	350115.6	131349	98280	5.0301	0.1886	5.8489	6.6809	0.9320	0.0426	1253	148270			
C8422	48hr	0.1952	24093	123427.3	417789	431253	5.1284	0.2058	5.8403	6.7333	1.0830	0.0440	1634	197422	198298	19	
C8423	48hr	0.2027	28230	139269.9	89437	89762	5.0824	0.2033	5.7115	6.6825	0.9510	0.0435	414	44520	44128	47	
C8424	48hr	0.1885	76261	404567.6	288206	258009	5.0119	0.1827	5.8947	6.7487	1.0820	0.0414	263	36927			
C8424	48hr	0.1958	84392	431011.2	83245	81744	5.0254	0.1927	5.7139	6.8241	1.1102	0.0424	214	29078	28875	49	
C8427	48hr	0.1887	16487	89910.91	228630	223500	5.0506	0.1840	5.8940	6.7107	1.0267	0.0426	212	28871			
C8427	48hr	0.1859	17372	91864								0.0418	246	32839	32802	14	
C8427	48hr	0.1863	85187	457257.1	487411	476761	5.0174	0.2168	5.7574	6.7747	1.0173	0.0428	832	102859			
C8428	48hr	0.1922	87944	457585	288206	258009	5.0119	0.1827	5.8947	6.7487	1.0820	0.0414	263	36927	35722	21	
C8428	48hr	0.1894	41068	218632.1	83245	81744	5.0254	0.1927	5.7139	6.8241	1.1102	0.0424	214	29078	28875	12	
C8429	48hr	0.1953	69480	385760.4													
C8429	48hr	0.1876	15732	83859.28													
C8429	48hr	0.1916	15632	82630.48													
C8430	48hr	0.1846	43059	233255.7													
C8430	48hr	0.1910	42785	224005.2													

Animal ID	Time Point	Wt. of Feces solubilized (g)	DPM from solubilized Feces	DPM's/g found from solubilization	Avg. DPM's/g found from solubilization 080800	Avg. DPM's/g found from solubilization (original)	% Recovery solubilization on 8/8/00 compared to original	Average % Recovery for each timepoint
C8421	12hr	0.2088	619111	2965091	2894319	3390019	85	95
		0.1931	545227	2823547				
C8422	12hr	0.1945	679273	3492406	3522034	2982693	118	
		0.2159	766804	3551663				
C8423	12hr	No Sample Left				799785	NS	
C8424	12hr	0.1735	747038	4305695	4299474	4148561	104	
		0.1983	851352	4293253				
C8427	12hr	0.1808	465107	2572494	2629325	3036609	87	
		0.1909	512787	2686155				
C8428	12hr	0.1860	852550	4583602	4542362	4509974	101	
		0.1837	826856	4501121				
C8429	12hr	0.2033	810663	3987521	3930450	4474675	88	
		0.2021	782810	3873380				
C8430	12hr	0.2140	153295	716331.8	675749	827921	82	
		0.2015	127986	635166.3				
C8421	24hr	0.2713	1514337	5581780	5552707	5822632	95	101
		0.1954	1079318	5523634				
C8422	24hr	0.1966	723296	3679023	3568235	3460076	103	
		0.1993	689069	3457446				
C8423	24hr	0.1926	1446094	7508276	6965786	6346882	110	
		0.1842	1183171	6423295				
C8424	24hr	0.2093	558373	2667812	2605425	2671982	98	
		0.1830	465376	2543038				
C8427	24hr	0.2107	1218523	5783213	5486894	6309211	87	
		0.2017	1046939	5190575				
C8428	24hr	0.2084	991029	4755417	4740681	4278045	111	
		0.2081	983469	4725944				
C8429	24hr	0.2236	859303	3843037	3645123	3548588	103	
		0.1942	669448	3447209				
C8430	24hr	0.2001	862864	4312164	4290316	4247633	101	
		0.2218	946746	4268467				
C8421	48hr	0.1816	63581	350115.6	356954	378824	94	105
		0.1798	65410	363793.1				
C8422	48hr	0.1952	24093	123427.3	131349	96260	136	
		0.2027	28230	139269.9				
C8423	48hr	0.1885	76261	404567.6	417789	431253	97	
		0.1958	84392	431011.2				
C8424	48hr	0.1897	16487	86910.91	89437	89762	100	
		0.1889	17372	91964				
C8427	48hr	0.1863	85187	457257.1	457411	475761	96	
		0.1922	87944	457565				
C8428	48hr	0.1894	41068	216832.1	286296	259009	111	
		0.1953	69480	355760.4				
C8429	48hr	0.1876	15732	83859.28	83245	81744	102	
		0.1916	15832	82630.48				
C8430	48hr	0.1846	43059	233255.7	228630	223590	102	
		0.1910	42785	224005.2				
Average =							100	

## **ATTACHMENT D**

### **Spiking Experiment to Determine Cause of Low Extraction Efficiencies Individual Results and Example Calculations**



## EXAMPLE CALCULATIONS

### Spiking Experiment Example Calculations

#### QC Spike Extraction Efficiencies

Dpm/g found from solubilization = dpm from solubilized feces / wt. of feces solubilized

Wt. of Tol extractant = Tare + extractant wt. (g) – wt. of empty extractant vial (g)

Dpm/g feces hmgnt found from extraction = dpm found from extractant / LSC aliquot weight (g) x wt. of Tol extractant  
/ aliquot wt. of feces homogenate extracted (g)

% Recovery = average of duplicated (dpm/g) / dpm's/g found from solubilization x 100

#### Solubilization Processing Efficiency

Wt. of feces (g) = Wt. of vial + control feces (g) – Tare wt. of empty vial for feces (g)

Wt. of <sup>14</sup>C-PDMS spiked (g) = Wt. of vial + feces + <sup>14</sup>C-PDMS spike (g) – Wt. of vial + control feces (g)

Dpm/g feces spiked = Wt. of <sup>14</sup>C-PDMS spiked (g) x specific activity of <sup>14</sup>C-PDMS, 350 cSt (mCi/g)  
x 2.22e<sup>9</sup> dpm/mCi / Wt. of feces (g)

Dilution found from solubilization = dpm from solubilized feces / wt. of feces solubilized

Recovery found 1 or 30 days after spiking = dpm's/g found from solubilization / dpm/g spiked x 100  
(if non-homogenized, use dpm/g spiked with dilution applied)

Sample ID	Wt. of Feces solubilized (g)	DPM from Feces Solubilized	DPM's/g found from solubilization	Aliquot Wt of feces homogenate extracted(g)	Weight of empty extractant vial (g)	Tare + extractant wt (g)	Wt of Tol extractant (g)	LSC allquot weight (g)	dpm found from extractant	dpm/g feces found from extraction	Average of duplicate (dpm/g)	% Recovery	Ave % Recovery for Timept.
Blank 1 Homogenized	0.1548	26.86	174	0.2306	5.7089	6.7520	1.0431	0.0425	17.94	1809	2127		
Blank 2 Homogenized	0.1990	26.33	132	0.2119	5.7209	6.8801	1.1592	0.0434	17.32	2183	2217		
Blank 3 Homogenized	0.1609	27.45	171	0.2136	5.8745	6.7694	1.0949	0.0424	17.54	2120	1937		
Spike A-1 Homogenized	0.1820	431181	2369126	0.1593	5.6670	6.8161	1.1491	0.0433	14806.0	2466561	2481592	105	108
Spike A-2 Homogenized	0.2374	575478	2424086	0.2016	5.7291	6.8002	1.0711	0.0423	18017.9	2263098	3432373	142	
Spike A-3 Homogenized	0.1431	418905	2827358	0.1618	5.7392	6.8867	1.1475	0.0430	38376.7	4801849	2298338	79	
Spike B-1 Homogenized	0.2215	819895	3701558	0.1872	5.7653	6.8753	1.1100	0.0432	30275.6	4155527	4157822	112	76
Spike B-2 Homogenized	0.2314	2325494	10049672	0.1870	5.7260	6.8827	1.1387	0.0431	34549.3	4872881	4895983	49	
Spike B-3 Homogenized	0.1715	1048572	6114122	0.2066	5.6940	6.8485	1.1525	0.0428	30940.8	4023323	4019993	86	
								0.0432	31105.6	4016864		Average =	92
Blank 1 NonHomogenized	0.2157	24.33	113	0.2627	5.5784	6.7234	1.1450	0.0428	15.23	1547	1756		
Blank 2 NonHomogenized	0.2214	23.84	108	0.2412	5.6467	6.7185	1.0718	0.0423	17.01	1787	1732		
Blank 3 NonHomogenized	0.1976	23.38	118	0.2515	5.6138	6.7451	1.1313	0.0430	15.22	1592	1760		
Spike A-1 NonHomogenized	0.2007	158794	791201	0.2178	5.7270	6.8193	1.0923	0.0417	5185.76	621273	633207	80	81
Spike A-2 NonHomogenized	0.2512	185789	739606	0.2515	5.7525	6.8894	1.1369	0.0421	5844.57	627559	629251	85	
Spike A-3 NonHomogenized	0.2244	175116	780374	0.2455	5.6636	6.8010	1.1374	0.0419	5876.08	630943	605479	78	
Spike B-1 NonHomogenized	0.1992	255231	1281280	0.1962	5.7127	6.8576	1.1449	0.0417	8170.41	1143343	1139051	89	88
Spike B-2 NonHomogenized	0.1894	244302	1289673	0.1837	5.6991	6.8665	1.1674	0.0421	7488.68	1127385	1130867	88	
Spike B-3 NonHomogenized	0.2014	257659	1279340	0.2074	5.6863	6.8280	1.1417	0.0428	8553.08	1100072	1115932	87	
								0.0428	8799.68	1131791		Average =	84

Sample ID	Wt. of Feces solubilized (g)	DPM from Solubilized Feces	DPM's/g found from solubilized feces	average DPM's/g found from solubilized feces	Allquot Wt of feces homogenate extracted (g)	Weight of empty extractant vial (g)	Tare + extractant wt (g)	Wt of Tol extractant (g)	LSC aliquot weight (g)	dpm found from extractant	dpm/g feces hmgnt found from extraction	Average of duplicate (dpm/g)	% Recovery	Ave % Recovery for Timept.
Blank 1	0.2012	23	114	133	0.1918	5.6799	6.8707	1.1908	0.0432	17	2443	2343		
Homogenized	0.2036	31	152						0.0443	16	2242			
Blank 2	0.1992	23	117	133	0.2019	5.6289	6.8330	1.2041	0.0436	17	2325	2223		
Homogenized	0.2017	30	149						0.0450	16	2120			
Blank 3	0.2050	27	132	134	0.2103	5.6251	6.8237	1.0949	0.0429	17	2063	1989		
Homogenized	0.1826	25	137						0.0435	16	1915			
Spike A-1	0.2175	508254	2336800	2509406	0.1866	5.6676	6.8186	1.1510	0.0440	25518	3577319	3530569	135	106
Homogenized	0.2022	582743	2882013						0.0442	24964	3483819			
Spike A-2	0.2060	506698	2459699	2530738	0.2027	5.7198	6.8928	1.1730	0.0441	15925	2089706	2076846	82	
Homogenized	0.2049	533104	2601776						0.0438	15922	2063986			
Spike A-3	0.1960	452159	2306934	2263887	0.2250	5.7247	6.8796	1.1549	0.0429	19233	2301185	2311849	102	
Homogenized	0.2045	454162	2220841						0.0432	19547	2322513			
Spike B-1	0.2113	684103	3237591	6375996	0.1863	5.6874	6.8444	1.1570	0.0440	21826	3080647	3087703	48	73
Homogenized	0.2190	2083654	9514402						0.0422	21029	3094758			
Spike B-2	0.2005	912501	4551127	4304158	0.2226	5.7425	6.8960	1.1535	0.0434	33190	3962671	3964176	92	
Homogenized	0.2092	848764	4057189						0.0440	33671	3965480			
Spike B-3	0.2092	764244	3653174	3946319	0.2212	5.7198	6.8833	1.1635	0.0437	28382	3175467	3128189	79	
Homogenized	0.2013	853404	4239463						0.0438	25855	3080811			
Blank 1	0.2203	34	154	142	0.1888	5.7213	6.8968	1.1755	0.0413	15	2261	2343	Average =	90
NonHomogenized	0.2078	27	130						0.0411	16	2424			
Blank 2	0.2041	27	132	133	0.2395	5.8649	6.9899	1.1250	0.0419	19	2130	1914		
NonHomogenized	0.2334	31	133						0.0415	15	1898			
Blank 3	0.2144	28	131	121	0.2632	5.7689	6.9309	1.1620	0.0417	17	1800	1802		
NonHomogenized	0.2407	27	112						0.0416	17	1804			
Spike A-1	0.2036	150033	736901	732256	0.2269	5.7296	6.8466	1.1170	0.0423	2591	301541	309826	42	44
NonHomogenized	0.2181	158692	727611						0.0420	2714	318111			
Spike A-2	0.2025	151088	746114	745617	0.2172	5.7272	6.8778	1.1506	0.0415	2820	334440	330733	44	
NonHomogenized	0.2254	167950	745120						0.0427	2838	327026			
Spike A-3	0.2003	149156	744663	749244	0.2217	5.6686	6.8231	1.1565	0.0416	2682	336314	342738	46	
NonHomogenized	0.2141	161394	753825						0.0424	2838	349162			
Spike B-1	0.1853	235057	1268521	1237402	0.2320	5.7095	6.8911	1.1816	0.0413	4344	535701	536107	43	43
NonHomogenized	0.2316	279375	1206282						0.0425	4477	536514			
Spike B-2	0.1983	249883	1260126	1271085	0.2105	5.7123	6.8709	1.1586	0.0418	3906	514325	513975	40	
NonHomogenized	0.1982	254101	1262043						0.0428	3994	513624			
Spike B-3	0.1933	237468	1228495	1234887	0.2058	5.6550	6.8358	1.1808	0.0418	4028	552897	567235	46	
NonHomogenized	0.2102	260917	1241280						0.0428	4318	581573		Average =	44



Due to technical error, weights were not obtained for the total sample (feces + water) upon homogenization for the Non-Homogenized samples. The dilution factor used here represents the theoretical dilution according to the SOP. When this theoretical dilution is compared to the average actual dilution for all the fecal samples done with this study, it differs by only 0.65%

0.003%

0.2516

actual average dilution of all fecal samples in study 9345 = 0.2516  
(174 carcasses per 30F theoretical = 0.2300

## **ATTACHMENT E**

### **Supplemental Dosing Experiment – Individual Results and Example Calculations**



## EXAMPLE CALCULATIONS

### Toluene Feces Extraction Results

Sample Weight (g) = Tare + Sample Wt. (g) - Vial Tare Wt. (g)

Homog. Wt. (g) = Tare + Sample + Diluent (g) - Vial Tare Wt. (g)

Wt. of feces aliquot = Tare Wt. + Feces aliquot (g) - Tare Wt. of feces aliquot vial (g)

Wt. of Toluene Extractant (g) = Tare + Toluene Extractant (g) - Tare Wt. of Extractant vial (g)

Conc. dpm's/g Toluene = Rep. Dpm's / Rep. Toluene extract wt. for LSC (g)

Dpm's/g toluene corrected = conc. dpm's/g toluene - average conc. dpm's/g toluene in control (for each sex)

Total dpm in feces homogenate extracted in toluene = avg. dpm's/g toluene x wt. of toluene extractant (g)  
/ wt. of feces aliquot (g) x Homog. Wt. (g)

Conc. extracted in toluene (dpm/g homogenate) = total dpm in feces homogenate extracted in toluene / homog. Wt. (g)

% Extracted vs. Solubilized = conc. extracted in toluene (dpm/g homogenate) / conc. dpm/g homogenate (solubilized) x 100

**THF Feces Extraction Results**

Sample Weight (g) = Tare + Sample Wt. (g) - Vial Tare Wt. (g)

Homog. Wt. (g) = Tare + Sample + Diluent (g) - Vial Tare Wt. (g)

Wt. of feces aliquot = Tare Wt. + Feces aliquot (g) - Tare Wt. of feces aliquot vial (g)

Wt. of THF Extractant (g) = Tare + THF Extractant (g) - Tare Wt. of Extractant vial (g)

Conc. dpm's/g THF = Rep. Dpm's / Rep. THF extract wt. for LSC (g)

Dpm's/g THF corrected = conc. dpm's/g THF - average conc. dpm's/g THF in control (for each sex)

Total dpm in feces homogenate extracted in THF = avg. dpm's/g THF x wt. of THF extractant (g)  
/ wt. of feces aliquot (g) x Homog. Wt. (g)

Conc. extracted in THF (dpm/g homogenate) = total dpm in feces homogenate extracted in THF / homog. Wt. (g)

% Extracted vs. Solubilized = conc. extracted in THF (dpm/g homogenate) / conc. dpm/g homogenate (solubilized) x 100

Combined conc. extracted in toluene and THF (dpm/g homogenate) = conc. extracted in toluene (dpm/g homogenate) +  
Conc. extracted in THF (dpm/g homogenate)

Combined % of extracted vs. solubilized =  $\frac{\text{Combined conc. extracted in toluene and THF (dpm/g homogenate)}}{\text{Conc. dpm/g homogenate (solubilizations)}} \times 100$

Combined toluene ext. + THF ext. + sol. Pellet % = combined % of extracted vs. solubilized + % left unextracted in pellet

### Solubilized Pellet

Sample Weight (g) = Tare + Sample Wt. (g) - Vial Tare Wt. (g)

Homog. Wt. (g) = Tare + Sample + Diluent (g) - Vial Tare Wt. (g)

Conc. dpm's/g = Rep. Dpm's / Rep. Wt. (g)

Dpm's/g corrected = conc. dpm's/g - conc. dpm's/g in control (for each sex)

Total dpm in sample = dpm's/g corrected x homog. Wt. (g)

Conc. dpm/g homogenate = total dpm in sample / homog. Wt. (g)

% left unextracted in pellet =  $\frac{\text{conc. dpm/g homogenate}}{\text{conc. dpm/g homogenate (original solubilized)}} \times 100$

### Feces QC Spikes

#### Spiking Standard Solution Calculations

Specific activity of 14C-PDMS, 350 cSt 0.27 mCi/g

Standard	Standard/Stock Added ID	Weight of Standard or stock added (g)	Total Soln. Weight (g)	[D4] mg/g	uCi/g THF	dpm/g
QC STK A	14C-PDMS	0.1023	0.9741	105.020	28.04	62246712
QC STK B	QC STK A	0.0880	0.9644	9.583	2.56	5679916

#### QC Spike Calculations 12hr

Feces	Spiked Stock Added ID	Weight of Spike Added (g)	Weight of empty extractant vial (g)	Tare Weight + Extractant (g)	Weight of extractant (g)	ug PDMS added in spike	uCi PDMS spiked	uCi PDMS/g Toluene spiked	dpm D4/g Toluene spiked
Blank	none		5.6355	6.8017	1.1662	0.00	0.00	0.00	0
Spike A	QC STK B	0.0032	5.6561	6.7710	1.1149	30.67	0.01	0.01	16303
Spike B	QC STK A	0.0110	5.6274	6.7228	1.0954	1155.22	0.31	0.28	625081
Spike C	QC STK A	0.0255	5.5998	6.7082	1.1084	2678.01	0.71	0.65	1432056

#### QC Spike Results 12hr

Feces	dpm D4/g Toluene spiked	LSC Aliquot weights 1,2 (g)	dpm theo	dpm actual	dpm - blank	% Recovery	average % Recovery of 2 aliquots	dpm/g found	Ave dpm/g found	Average % Recovery
Blank	0	0.0436	0	16	-1			0	0	
		0.0442	0	18	1			0		
Spike A	16303	0.0443	722	666	649	90	90	14650	14746	90
		0.044	717	670	653	91	91	14841		
Spike B	625081	0.0445	27816	26383	26366	95	95	592494	595429	95
		0.0434	27129	25986	25969	96	96	598364		
Spike C	1432056	0.0430	61578	60127	60110	98	97	1397907	1388591	97
		0.0442	63297	60981	60964	96	94	1379276		94

**Feces QC Spikes**

**Spiking Standard Solution Calculations**

Specific activity of 14C-PDMS, 350 cSt 0.27 mCi/g

Standard	Standard/Stock Added ID	Weight of stock added (g)	Total Soln. Weight (g)	[D4] mg/g	uCi/g THF	dpm/g
QC STK A	14C-PDMS	0.1023	0.9741	105.020	28.04	62246712
QC STK B	QC STK A	0.0880	0.9644	9.583	2.56	5679916

**QC Spike Calculations 24hr**

Feces	Spiked Stock Added ID	Weight of Spike Added (g)	Weight of empty extractant vial (g)	Tare Weight + Extractant (g)	Weight of extractant (g)	ug PDMS added in spike	uCi PDMS		uCi PDMS/g		dpm D4/g	
							spiked	spiked	Toluene	spiked	Toluene	spiked
Blank	none		5.6406	6.8239	1.1833	0.00	0.00	0.00	0.00	0.00	0	0
Spike A	QC STK B	0.0035	5.6534	6.7756	1.1222	33.54	0.01	0.01	0.01	0.01	17715	17715
Spike B	QC STK A	0.0110	5.6897	6.8074	1.1177	1155.22	0.31	0.31	0.28	0.28	612610	612610
Spike C	QC STK A	0.0260	5.6661	6.8588	1.1927	2730.52	0.73	0.73	0.61	0.61	1356933	1356933

**QC Spike Results 24hr**

Feces	dpm D4/g Toluene		LSC Aliquot weights 1,2		dpm theo	dpm actual	dpm - blank	% Recovery	average % Recovery of 2 aliquots	Ave dpm/g		Average % Recovery
	spiked	0	(g)	(g)						dpm/g found	dpm/g found	
Blank	0	0.0438	0.0473	0	0	16	-1			0	0	
Spike A	17715	0.0434	0.0439	769	645	629	82	83		14707	14482	83
Spike B	612610	0.0467	0.0433	778	672	656	84	92		564421	14932	92
Spike C	1356933	0.043	0.0435	28609	26376	26360	92	95		564400	564443	95
				26526	24455	24439	95			1284267	564400	95
				58348	55240	56224	95			1286657	1284267	90
				59027	56090	56074	95			1289046	1286657	90

### Feces QC Spikes

#### Spiking Standard Solution Calculations

Specific activity of 14C-PDMS, 350 cSt

0.27 mCi/g

Standard	Standard/Stock Added ID	Weight of stock added (g)	Total Soln. Weight (g)	[D4] mg/g	uCi/g THF	dpm/g
QC STK A	14C-PDMS	0.1023	0.9741	105.020	28.04	62246712
QC STK B	QC STK A	0.0880	0.9644	9.583	2.56	5679916

#### QC Spike Calculations 48hr

Feces	Spiked Stock Added ID	Weight of Spike Added (g)	Weight of empty extractant vial (g)	Tare Weight + Extractant (g)	Weight of extractant (g)	ug PDMS added in spike	uCi PDMS spiked	uCi PDMS/g Toluene spiked	dpm D4/g Toluene spiked
Blank	none		6.1200	7.1988	1.0788	0.00	0.00	0.00	0
Spike A	QC STK B	0.0025	6.1554	7.2001	1.0447	23.96	0.01	0.01	13592
Spike B	QC STK A	0.0109	6.1552	7.2759	1.1207	1144.72	0.31	0.27	605416
Spike C	QC STK A	0.0257	6.1739	7.2855	1.1116	2699.01	0.72	0.65	1439133

#### QC Spike Results 48hr

Feces	dpm D4/g Toluene spiked	LSC Aliquot weights 1,2 (g)	dpm theo	dpm actual	dpm - blank	% Recovery	average % Recovery of 2 aliquots	dpm/g found	Ave dpm/g found	Average % Recovery
Blank	0	0.0438	0	17	0			0	0	
		0.0419	0	17	0			0		
Spike A	13592	0.0434	590	652	635	108	108	14631	14713	108
		0.044	598	668	651	109		14795		
Spike B	605416	0.0435	26336	25152	25135	95	95	577816	575049	95
		0.0434	26275	24854	24837	95		572281		
Spike C	1439133	0.0435	62602	58915	58898	94	93	1353977	1342000	93
		0.0438	63034	58272	58255	92	99	1330023		99

**Feces QC Spikes**

**Spiking Standard Solution Calculations**

Specific activity of 14C-PDMS, 350 cSt 0.27 mCi/g

Standard	Standard/Stock Added ID	Weight of stock added (g)	Total Soln. Weight (g)	[D4] mg/g	uCi/g THF	dpm/g
QC STK A	14C-PDMS	0.1023	0.9741	105.020	28.04	62246712
QC STK B	QC STK A	0.0880	0.9644	9.583	2.56	5679916

**QC Spike Calculations 4-9-01 THF**

Feces	Spiked Stock Added ID	Weight of Spike Added (g)	Weight of empty extractant vial (g)	Tare Weight + Extractant (g)	Weight of extractant (g)	ug PDMS added in spike	uCi PDMS spiked	uCi PDMS/g Toluene spiked	dpm D4/g Toluene spiked
Blank	none		5.5928	6.8469	1.2541	0.00	0.00	0.00	0
Spike A	QC STK B	0.0030	5.6346	6.8977	1.2631	28.75	0.01	0.01	13490
Spike B	QC STK A	0.0112	5.6235	6.8911	1.2676	1176.22	0.31	0.25	549987
Spike C	QC STK A	0.0258	5.6268	6.8917	1.2649	2709.52	0.72	0.57	1269638

**QC Spike Results THF**

Feces	dpm D4/g Toluene spiked	LSC Aliquot weights 1,2 (g)	dpm theo	dpm actual	dpm - blank	% Recovery	average % Recovery of 2 aliquots	Ave dpm/g found	Average % Recovery
Blank	0	0.0437	0	15	0			0	
		0.0454	0	15	0			0	
Spike A	13490	0.0455	614	556	541	88	87	11890	11707
		0.0453	611	537	522	85		11523	
Spike B	549987	0.0451	24804	21887	21872	88	88	484967	482036
		0.0458	25189	21958	21943	87		479105	
Spike C	1269638	0.0451	57261	52675	52660	92	93	1167627	1177458
		0.0461	58530	54749	54734	94	89	1187289	

### 12 Hour Feces - Toluene Extraction on 3/28/01

Sample ID	actual injected	LSC (~50ul)		Average LSC CPM's		% System Recovery
		CPM detected	CPM	CPM's	detected at ~ 7 min	
C9230-1	100	18883		18934	39463.00	104
C9230-2	100	18984				
C9232-1	100	24599		24694	48807.00	99
C9232-2	100	24788				
C9238-1	100	8056		8080	14870.00	92
C9238-2	100	8104				
C9239-1	100	27		28	BLQ	
C9239-2	100	29				

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### 24 Hour Feces - Toluene Extraction on 3/29/01

Sample ID	actual injected	LSC (~50ul)		Average LSC CPM's		% System Recovery
		CPM detected	CPM	CPM's	detected at ~ 7 min	
C9230-1	100	28412		28191	58767.00	104
C9230-2	100	27969				
C9232-1	100	26233		26148	54538.00	104
C9232-2	100	26063				
C9238-1	100	29497		29365	61916.00	105
C9238-2	100	29232				
C9239-1	100	25429		25525	51521.00	101
C9239-2	100	25620				

104

### 48 Hour Feces - Toluene Extraction on 3/30/01

Sample ID	actual injected	LSC (~50ul)		Average LSC CPM's		% System Recovery
		CPM detected	CPM	CPM's	detected at ~ 7 min	
C9230-1	100	3140		3140	5122.00	82
C9230-2	100	3140				
C9232-1	100	2858		2809	5264.00	94
C9232-2	100	2760				
C9238-1	100	5414		5473	9357.00	85
C9238-2	100	5531				
C9239-1	100	4184		4156	7046.00	85
C9239-2	100	4127				

86

BLQ = below quantitation limit of HPLC Detector

Dosing solution S.A.= 599400 DPMs/mg  
BKG= 392 DPM/g Female  
BKG= 383 DPM/g Male

**Feces**

Sample ID	Time Pt.	Group/ Sex	Vial Tare Wt.(g)	Tare + Sample Wt.(g)	Sample Wt.(g)	Tare+ Sample Diluent(g)	Homog. Wt.(g)	Tare wt of feces aliquot vial(g)	Tare Wt.+ feces aliquot(g)	Wt of feces aliquot(g)	Tare Wt. Of Extractant Vial(g)	Tare + Toluene Extractant (g)	Wt. Of Toluene Extractant (g)	Rep. Toluene Extract Wt. For LSC (g)
C9233	24hr	M	98.87	104.34	5.47	120.19	21.32	5.5314	5.7185	0.1871	6.1593	7.3058	1.1465	0.0426
C9240	24hr	F	100.33	105.34	5.01	120.41	20.08	5.5277	5.6954	0.1677	6.2181	7.3700	1.1519	0.0436
C9230	12hr	M	98.79	101.44	2.65	109.90	11.11	5.5044	5.7745	0.2701	6.2000	7.3458	1.1458	0.0418
C9230	24hr	M	95.68	98.41	2.73	107.35	11.67	5.4982	5.6833	0.1851	6.2291	7.3865	1.1574	0.0425
C9230	48hr	M	100.73	105.72	4.99	119.38	18.65	4.9520	5.0911	0.1391	6.1887	7.3343	1.1456	0.0439
C9232	12hr	M	96.17	99.49	3.32	110.27	14.10	5.5167	5.7734	0.2567	6.1636	7.3170	1.1534	0.0441
C9232	24hr	M	98.65	101.99	3.34	111.48	12.83	5.5089	5.7269	0.2180	6.2379	7.3725	1.1346	0.0429
C9232	48hr	M	100.44	104.94	4.50	117.57	17.13	4.9768	5.1837	0.2069	6.2108	7.3522	1.1414	0.0444
C9238	12hr	F	97.91	100.46	2.55	110.02	12.11	5.5156	5.7472	0.2316	6.1898	7.3887	1.1989	0.0430
C9238	24hr	F	98.67	100.63	1.96	106.66	7.99	5.5451	5.7210	0.1759	6.1626	7.3138	1.1512	0.0429
C9238	48hr	F	95.82	101.67	5.85	117.88	22.06	5.0025	5.1808	0.1783	6.1624	7.2434	1.0810	0.0435
C9239	12hr	F	95.76	96.13	0.37	97.11	1.35	5.5225	5.7774	0.2549	6.1939	7.2690	1.0751	0.0441
C9239	24hr	F	96.15	100.19	4.04	111.50	15.35	5.5125	5.6958	0.1833	6.1376	7.2692	1.1316	0.0433
C9239	48hr	F	97.44	102.17	4.73	115.69	18.25	5.0015	5.1889	0.1874	6.2321	7.3358	1.1037	0.0430
														0.0446
														0.0445
														0.0446
														0.0442



**Feces**

Sample ID	Time Pt.	Group/ Sex	Rep. DPM's	Conc. DPM's/g toluene	DPM's/g toluene corrected	Avg. DPM's/g toluene	Total DPM In feces			Conc. dpm/g homogenate (solubilizations)	% of extracted vs solubilized
							homogenate extracted in toluene	Conc. Extracted in toluene (dpm/g homogenate)			
C9233	24hr	M	17	399							
C9240	24hr	F	17	394							
C9230	12hr	M	19742	472297	471914	469318	22119013	1990910	2270901	87.7%	
C9230	24hr	M	19852	467106	466723	670340	48915111	4191526	5719188	73.3%	
C9230	48hr	M	29709	675205	674822	73655	11313292	606611	789688	76.8%	
C9232	12hr	M	29248	666241	665858	591390	37466871	2657225	2922228	90.9%	
C9232	24hr	M	3284	73632	73249	622575	41572341	3240245	4265658	76.0%	
C9232	48hr	M	3283	74444	74061	65864	6224203	363351	487924	74.5%	
C9238	12hr	F	25725	599650	599267	196314	12306664	1016240	1199244	84.7%	
C9238	24hr	F	25925	583896	583513	700622	36636619	4585309	6216968	73.8%	
C9238	48hr	F	27438	626438	626055	129051	17260031	782413	1094462	71.5%	
C9239	12hr	F	27257	619477	619094	292	1660	1230	2593		
C9239	24hr	F	2989	67472	67089	598758	56740128	3696425	5317172	69.5%	
C9239	48hr	F	2887	65023	64640	97490	10478590	574169	783933	73.2%	
			8424	195907	195515				average =	77.4%	
			8473	197506	197114				stdev =	7.06%	
			30844	709057	708665						
			30560	692971	692578						
			5661	128367	127975						
			5782	130519	130127						
			29	670	278						
			30	698	306						
			26590	596188	595796						
			26794	602112	601720						
			4376	98117	97724						
			4316	97647	97255						



### 12 Hour Feces - THF Extraction on 4/9/01

Sample ID	actual injected	LSC (~50ul) CPM	Average LSC CPM's	HPLC (~100ul) CPM detected at ~ 7 min	% System Recovery
		detected			
C9230-1	100	2174	2152	3548.00	82
C9230-2	100	2129			
C9232-1	100	1151	1079	1544.00	72
C9232-2	100	1007			
C9238-1	100	1593	1610	2644.00	82
C9238-2	100	1627			
C9239-1	100	19	17	BLQ	
C9239-2	100	15			
					79

### 24 Hour Feces - THF Extraction on 4/9/01

Sample ID	actual injected	LSC (~50ul) CPM	Average LSC CPM's	HPLC (~100ul) CPM detected at ~ 7 min	% System Recovery
		detected			
C9230-1	100	5801	5876	11103.00	94
C9230-2	100	5950			
C9232-1	100	4212	4337	7956.00	92
C9232-2	100	4462			
C9238-1	100	6937	6999	15069.00	108
C9238-2	100	7060			
C9239-1	100	5441	5475	9097.00	83
C9239-2	100	5509			
					94

### 48 Hour Feces - THF Extraction on 4/9/01

Sample ID	actual injected	LSC (~50ul) CPM	Average LSC CPM's	HPLC (~100ul) CPM detected at ~ 7 min	% System Recovery
		detected			
C9230-1	100	392	404	BLQ	
C9230-2	100	415			
C9232-1	100	420	426	BLQ	
C9232-2	100	432			
C9238-1	100	1049	1043	1629.00	78
C9238-2	100	1036			
C9239-1	100	679	692	1257.00	91
C9239-2	100	704			
					85

BLQ = below quantitation limit of HPLC Detector

Dosing solution S.A.= 599400 DPMs/mg  
BKG= 345  
BKG= 383  
μCi/mg= 0.27 μCi/mg=

Feces

Sample ID	Time Pt.	Group/ Sex	Vial Tare Wt.(g)	Tare + Sample Wt.(g)	Sample Wt.(g)	Tare + Sample Diluent (g)	Tare wt of Feces aliquot vial (g)	Tare Wt.+ Feces aliquot (g)	Wt of Feces aliquot (g)	Tare Wt. Of Extractant Vial (g)	Tare + THF Extractant (g)	Wt. Of THF Extractant (g)	Rep. THF Extract Wt. For LSC (g)
C9233	24hr	M	98.87	104.34	5.47	120.19	5.6314	5.7185	0.1871	5.6429	7.0336	1.3907	0.0457
C9240	24hr	F	100.33	105.34	5.01	120.41	5.5277	5.6954	0.1677	5.6461	6.9983	1.3522	0.0461
C9230	12hr	M	98.79	101.44	2.65	109.90	5.5044	5.7745	0.2701	5.6880	7.1300	1.4420	0.0457
C9230	24hr	M	95.68	98.41	2.73	107.35	5.4982	5.6833	0.1851	5.6089	6.9621	1.3532	0.0452
C9230	48hr	M	100.73	105.72	4.99	119.38	4.9520	5.0911	0.1391	5.6881	7.0069	1.3188	0.0466
C9232	12hr	M	96.17	99.49	3.32	110.27	5.5167	5.7734	0.2567	5.6727	7.1184	1.4457	0.046
C9232	24hr	M	98.65	101.99	3.34	111.48	5.5089	5.7269	0.2180	5.6781	7.0648	1.3867	0.0459
C9232	48hr	M	100.44	104.94	4.50	117.57	4.9768	5.1837	0.2069	5.6659	6.9892	1.3233	0.0469
C9238	12hr	F	97.91	100.46	2.55	110.02	5.5156	5.7472	0.2316	5.6217	6.9582	1.3365	0.0454
C9238	24hr	F	98.67	100.63	1.96	106.66	5.5451	5.7210	0.1759	5.6448	6.9924	1.3476	0.045
C9238	48hr	F	95.82	101.67	5.85	117.88	5.0025	5.1808	0.1783	5.6230	7.0007	1.3777	0.0458
C9239	12hr	F	95.76	96.13	0.37	97.11	5.5225	5.7774	0.2549	5.6954	7.2179	1.5225	0.0453
C9239	24hr	F	96.15	100.19	4.04	111.50	5.5125	5.8958	0.1833	5.6202	6.9960	1.3758	0.0465
C9239	48hr	F	97.44	102.17	4.73	115.69	5.0015	5.1889	0.1874	5.6508	7.0142	1.3634	0.0467
													0.0452
													0.0463

**Feces**

Sample ID	Time	Group/Pl	Sex	Rep. DPM's	Conc. DPM's/g THF	DPM's/g THF corrected	Avg. DPM's/g THF	Total DPM in feces extracted in THF	Conc. extracted in THF (dpm/g homogenate)	Conc. Extracted in toluene (dpm/g homogenate)	Combined Conc. extracted in toluene and THF (dpm/g homogenate)	Conc. dpm/g homogenate (solubilizations)	%extracted(THF) vs solubilized	Combined% of extracted vs solubilized	Combined toluene ext + THF ext + sol. Pellet %
C9233	24hr	M	M	19	416										
C9240	24hr	F	F	16	351										
C9230	12hr	M	M	2276	49803	49420	48916	2901415	261153	1990910	2252084	2270901	11.5%	99.2%	101.2%
C9230	24hr	M	M	2230	48796	48413	133631	11400754	976928	4191526	5168455	5719188	17.1%	90.4%	91.0%
C9230	48hr	M	M	6074	134381	133997	8952	1582834	84870	606611	691481	789688	10.7%	87.6%	87.7%
C9232	12hr	M	M	6228	133648	133265	25156	1997585	141673	2657225	2798898	2922228	4.8%	95.8%	96.1%
C9232	24hr	M	M	410	9213	8830	97475	7955097	620039	3240245	3860283	4285658	14.5%	90.5%	91.4%
C9232	48hr	M	M	435	9457	9073	9301	1019047	59489	363351	422840	487924	12.2%	86.7%	87.2%
C9238	12hr	F	F	1205	26196	25812	36959	2582805	213279	1016240	1229519	1199244	17.8%	102.5%	103.6%
C9238	24hr	F	F	1055	24882	24499	160708	9837382	1231212	4585309	5816521	6216968	19.8%	93.6%	94.2%
C9238	48hr	F	F	4411	96100	95717	23452	3997548	181213	782413	963626	1094462	16.6%	88.0%	89.0%
C9239	12hr	F	F	4672	99616	99233	51	410	304	1230	1534	2593			
C9239	24hr	F	F	439	9564	9181	125093	14412366	938916	3698425	4635341	5317172	17.7%	87.2%	88.1%
C9239	48hr	F	F	452	9805	9421	15479	2055275	112618	574169	686787	783933	14.4%	87.6%	88.2%
				1688	36740	36395						<b>Average =</b>	<b>14.3%</b>	<b>91.7%</b>	<b>92.5%</b>

Dosing solution S.A.= 0.27 µCi/mg= 598400 DPMs/mg

BKG= 1000 DPM/g Female

BKG= 566 DPM/g Male

Feces

Animal ID	Time Pt.	Group/ Sex	Vial Tare Wt.(g)	Tare + Sample Wt.(g)	Sample Wt.(g)	Tare+Sample +Diluent (g)	Homog. Wt. (g)	Rep. Wt. (g)	Rep. DPM's	Conc. DPM's/g	DPM's/g corrected	Total DPM in sample	Conc. dpm/g homogenate	Conc. dpm/g homogenate (original) (solubilized)	% left un- extracted in pellet
C9233	24hr	M	98.87	104.34	5.4700	120.19	21.32	0.0477	27	566.04					
C9240	24hr	F	100.33	105.34	5.0100	120.41	20.08	0.0280	28	1000.00			46764	2270901	2.1%
C9230	12hr	M	98.79	101.44	2.6500	109.90	11.11	0.0633	2996	47330	46764	519550	34112	5719188	0.6%
C9230	24hr	M	95.68	98.41	2.7300	107.35	11.67	0.0295	1023	34678	34112	398086	2161	789688	0.3%
C9230	48hr	M	100.73	105.72	4.9900	119.38	18.65	0.0209	57	2727	2161	40307	9014	2922228	0.3%
C9232	12hr	M	96.17	99.49	3.3200	110.27	14.10	0.0357	342	9580	9014	127094	38156	4265658	0.9%
C9232	24hr	M	98.65	101.99	3.3400	111.48	12.83	0.054	2091	38722	38156	489544	2541	487924	0.5%
C9232	48hr	M	100.44	104.94	4.5000	117.57	17.13	0.0354	110	3107	2541	43533	12384	1199244	1.0%
C9238	12hr	F	97.91	100.46	2.5500	110.02	12.11	0.0464	621	13384	12384	149966	38367	6216968	0.6%
C9238	24hr	F	98.67	100.63	1.9600	106.66	7.99	0.0158	622	39367	38367	308553	10781	1094462	1.0%
C9238	48hr	F	95.82	101.67	5.8500	117.88	22.06	0.0247	291	11781	10781	237837	478	2593	
C9239	12hr	F	95.76	96.13	0.3700	97.11	1.35	0.0433	64	1478	478	645	49960	5317172	0.9%
C9239	24hr	F	96.15	100.19	4.0400	111.50	15.35	0.025	1274	50960	49960	76886	4311	783933	0.5%
C9239	48hr	F	97.44	102.17	4.7300	115.69	18.25	0.0514	273	5311	4311	78681			

**Date:** September 10, 2001  
**To:** Marina Jovanovic  
**Subject:** Analysis of the data from study 9345

## Summary

The objective of this study was to determine the amount of polydimethylsiloxane (PDMS, 350 cst) absorbed from the gastrointestinal tract of Fischer 344 rats and to determine if there were any differences in absorption or distribution between males and females. A dose of 1000 mg/kg of radio-labeled ( $^{14}\text{C}$ ) PDMS was administered by oral gavage. In females, 93.6% of administered radioactivity was recovered. Radioactivity as percent of administered dose was significantly greater than zero for all compartments except cage rinse, carbon dioxide, blood, eyes and fat. The total percent of administered radioactivity retained in or on the body was significantly greater than zero but less than one one-hundredth of one percent (0.0039 %). In males, 97.4 % of administered radioactivity was recovered. Radioactivity as percent of administered dose was significantly greater than zero for all compartments except the gastrointestinal contents, blood, empty carcass and fat. As in the females, the total percent of administered radioactivity retained in or on the body was significantly greater than zero but less than one one-hundredth of one percent (0.0052 %). The radioactivity content of the feces in males was significantly greater than in females (97.4 % vs. 93.6%), resulting in significantly greater radiolabel excretion in males compared to females. Fecal radioactivity content accounted for 99.98% of total recovered radiolabel in both females and males.

## Introduction

The objective of this study was to determine the amount of polydimethylsiloxane (PDMS) absorbed from the gastrointestinal tract of Fischer 344 rats and to determine if there were any differences in absorption and distribution between males and females.

## Methods

The response in each analysis was percent of administered radioactivity recovered in a given sample. All statistical analyses were carried out using SAS®, v. 8.0. The probability of Type I error ( $\alpha$ ) was 5 %. Comparisons between males and females were made using two-tailed t-tests. A one-tailed t-test was used to test the hypothesis that the amount of radioactivity in a sample was significantly greater than zero.

## Results


*Females:* 93.6 % of administered radioactivity was recovered. Radioactivity as percent of administered dose was significantly greater than zero for all compartments except cage rinse, carbon dioxide, blood, eyes and fat. The total percent of administered radioactivity retained in or on the body was significantly greater than zero but less than one one-hundredth of one percent (0.0039 %). Fecal radioactivity content accounted for 99.98% of total recovered radiolabel.

*Males:* 97.4 % of administered radioactivity was recovered. Radioactivity as percent of administered dose was significantly greater than zero for all compartments except the gastrointestinal contents, blood, empty carcass and fat. The total percent of administered radioactivity retained in or on the body was significantly greater than zero but less than one one-hundredth of one percent (0.0052 %). Fecal radioactivity content accounted for 99.98% of total recovered radiolabel.

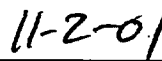
*Gender effects:* The radioactivity content of the feces in males was significantly greater than in females (97.4 % vs. 93.6 %), resulting in significantly greater radiolabel excretion in males compared to females. Total recovery in males was significantly greater than in females.

**Documentation**

A copy of the SAS® Log, the SAS/Lab® output and the SAS® output for this analysis is filed with the raw data in the study file.



Kathleen P. Plotzke  
Manager, Toxicology  
for Robert H. Gallavan, Jr.  
Biostatistician Specialist



Date

**Memorandum**

**To:** Marina Jovanovic  
**From:** J.M. Regan  
**Date:** 11/06/2001  
**Re:** Study 9345 - Results of Part 2 (Whole-body autoradiography)

---

**Title:** Disposition of Polydimethylsiloxane, 350 cst in Fischer 344 Rats Following a Single Exposure by Oral Gavage

**Introduction**

The objective of this study was to determine absorption and distribution of the test material  $^{14}\text{C}$ -polydimethylsiloxane, viscosity 350 cst ( $^{14}\text{C}$ -PDMS) in Fischer 344 rats after single exposure by oral gavage. The whole-body autoradiography (WBA) portion of this study was performed concurrently with the mass balance analysis. WBA is a method used for the *in vivo* determination of the distribution and disposition of radioactivity in tissues and may be used for the visual assessment of the transient time of radioactivity through the gastrointestinal (GI) tract. Experimental design and specific information regarding the test system, test article, and dosing may be found in the study protocol and in the main body of the final report.

**Methods**

One animal of each gender was euthanized at selected time points (12, 24, 48, and 96 hours) by  $\text{CO}_2$  asphyxiation following a single exposure by oral gavage of  $^{14}\text{C}$ -PDMS, 350 cst. with targeted radioactivity of  $50\mu\text{Ci/animal}$  and a target dose of 1000 mg/kg of body weight for each animal. Immediately following euthanasia, each animal was rapidly frozen in a hexane/dry ice mixture at approximately  $-75^\circ\text{C}$ . and stored at  $-80^\circ\text{C}$ . The frozen carcasses were embedded in a 4% aqueous solution of carboxymethylcellulose (Sigma Chemical Company, St. Louis, MO) which, when frozen, supported the carcass for sectioning on the CryoMacrocut® cryomicrotome (Leica, Deerfield, IL) with temperature maintained at approximately  $-25^\circ\text{C} \pm 5^\circ$ . Parasagittal sections of approximately  $40\mu$  in thickness were collected at various levels to include all major organs and tissues of interest. The non-dehydrated sections were then placed immediately onto Kodak BioMax MR film (Eastman Kodak Company, Rochester, NY) and exposed at  $-80^\circ\text{C}$ . for 2, 3, and 4 weeks. One representative section from each level was dehydrated within the

cryochamber for 48 to 72 hours and retained as a reference for comparison with the film. At the end of the exposure periods, films were developed on a Cordell™ MXR-14 automatic film processor (Cordell, Peabody, MA). The images were digitally acquired from the film with the Hewlett-Packard ScanJet Pro (Palo Alto, CA) with output in grayscale at a resolution of 200 PPI (pixels per inch). Figures in this report are scanned images of the original autoradiographs.

## Results

Exposure times were determined empirically after developing the films following two, three, and four weeks exposure at -80°C. There appeared to be no discernable difference in the intensity of the radioactivity between films developed at three and four weeks. All original films were reviewed and evaluated visually for intensity based on a gradient scale of grayness (0-4+) with comparison to background as zero.

Twelve hours following the oral dose in both male and female rats a high amount (4+) of radioactivity appeared to be concentrated in the contents of the lower portion gastrointestinal tract (cecum and colon) as seen in Figures 1 and 2. A minimal amount (1+) of radioactivity was noted on the ventral and dorsal surface of both animals as possible contamination on the coats of the animals by the test material. There was a minimal amount of smearing of radioactivity caused by the physical properties of the test material, the high concentration of radioactivity, and the drag of the knife through this area during sectioning. There was no disposition of radioactivity noted in any other organs or tissues.

At 24 hours after dosing the distribution pattern of radioactivity was similar to that observed at twelve hours. Both animals showed a high level (3-4+) of radioactivity concentrated in the contents of the small intestine, cecum, and colon (Figures 3 and 4). There was a small amount of radioactivity noted in the residual contents of the stomach of both animals.

Again at 48 hours following the dose, the radioactivity was limited to the GI tract but concentration levels were notably decreased. Low amounts (1+) were noted in the small intestine and cecum with a moderate amount (2+) in the colon of both animals (Figures 5 and 6). Again, there was no disposition of radioactivity noted in any other organs or tissues.

At 96 hours after the dose, there appeared to be total elimination since no radioactivity was observed in either of the animals (Figures 7 and 8). Although no images appear, Figures 7 and 8 are included in this report to show the background of the film after exposure to the sections.

In conclusion, the radioactivity appeared to be concentrated in the contents of the gastrointestinal tract of both male and female animals with no radioactivity noted in other organs or tissue. Both sexes showed comparatively similar patterns of disposition at each time point and the transient time of radioactivity through the gastrointestinal tract was similar with total elimination of radioactivity by 96 hours in both sexes.

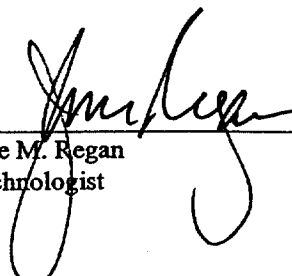
Frozen carcasses from Group 6 were stored at -80° C for possible future processing if the interpretation of films from Group 5 were equivocal or results obscured by artifact. All results were obtained from Group 5 eliminating the necessity to process from these spares (Group 6).

#### Records To Be Archived

Frozen carcasses, as well as the non-dehydrated sections were authorized for disposal upon finalization of the study. Films, dehydrated references sections, and processing records are maintained in HES archives of Dow Corning Corporation, Midland, MI.

#### List of Figures

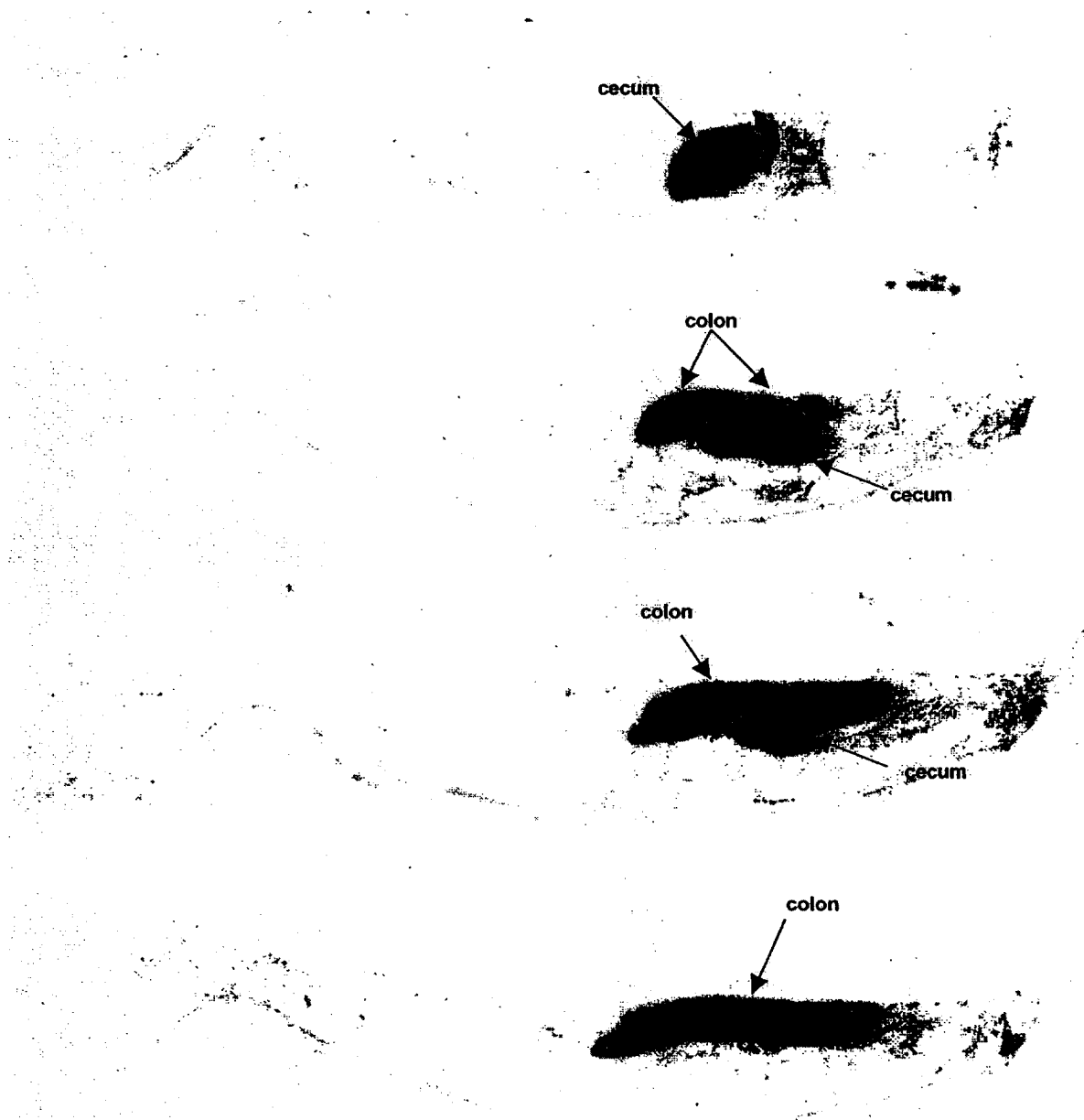
1. Whole Body Autoradiograph of Female Fischer 344 Rat 12 Hours Following Administration of a Single Dose of Polydimethylsiloxane, 350 cst
2. Whole Body Autoradiograph of Male Fischer 344 Rat 12 Hours Following Administration of a Single Dose of Polydimethylsiloxane, 350 cst
3. Whole Body Autoradiograph of Female Fischer 344 Rat 24 Hours Following Administration of a Single Dose of Polydimethylsiloxane, 350cst
4. Whole Body Autoradiograph of Male Fischer 344 Rat 24 Hours Following Administration of a Single Dose of Polydimethylsiloxane, 350 cst
5. Whole Body Autoradiograph of Female Fischer 344 Rat 48 Hours Following Administration of a Single Dose of Polydimethylsiloxane, 350 cst
6. Whole Body Autoradiograph of Male Fischer 344 Rat 48 Hours Following Administration of a Single Dose of Polydimethylsiloxane, 350 cst
7. Whole Body Autoradiograph of Female Fischer 344 Rat 96 Hours Following Administration of a Single Dose of Polydimethylsiloxane, 350 cst
8. Whole Body Autoradiograph of Male Fischer 344 Rat 96 Hours Following Administration of a Single Dose of Polydimethylsiloxane, 350 cst

  
\_\_\_\_\_  
Jane M. Regan  
Technologist

11/6/01  
\_\_\_\_\_  
Date

## Figure 1

Whole Body Autoradiograph of Female Fischer 344 Rat 12 Hours Following Administration of a Single Oral Dose of Polydimethylsiloxane, 350 cst.

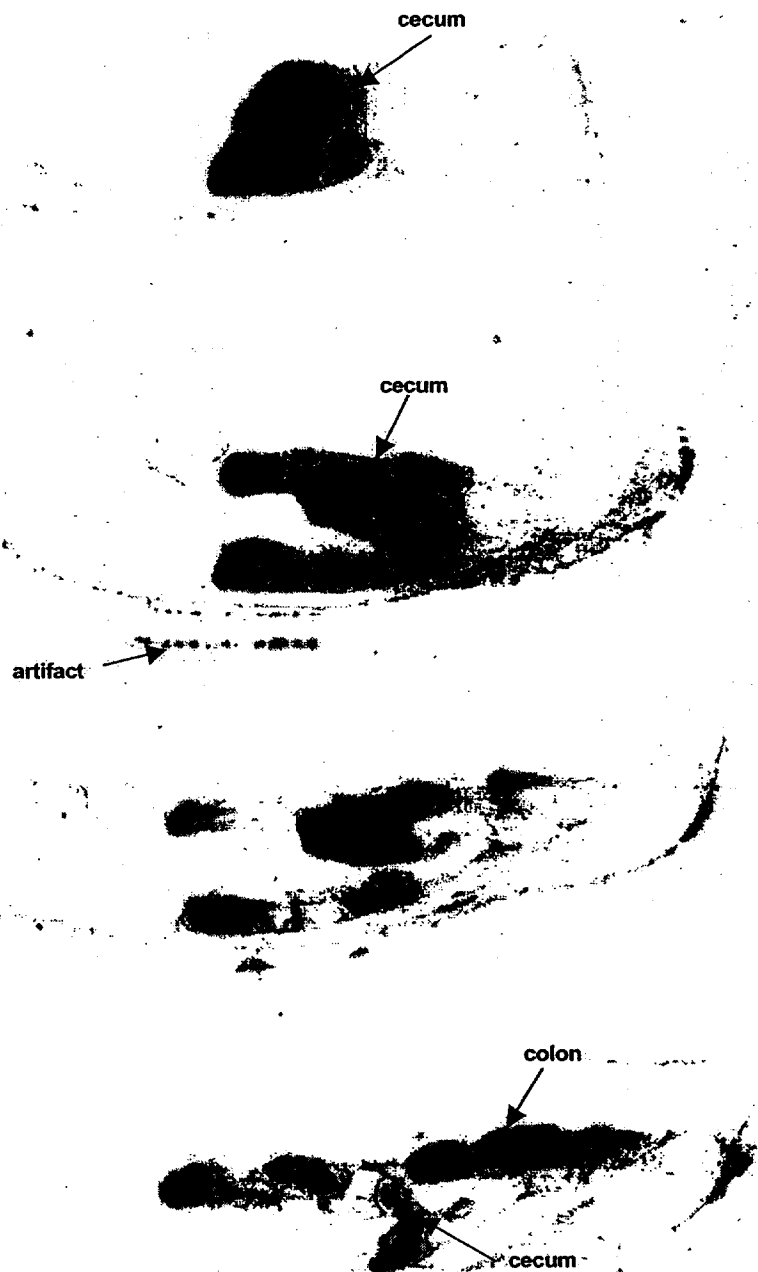


C8431

Female 12 hour

## Figure 2

Whole Body Autoradiograph of Male Fischer 344 Rat 12 Hours Following  
Administration of a Single Oral Dose of Polydimethylsiloxane, 350 cst.

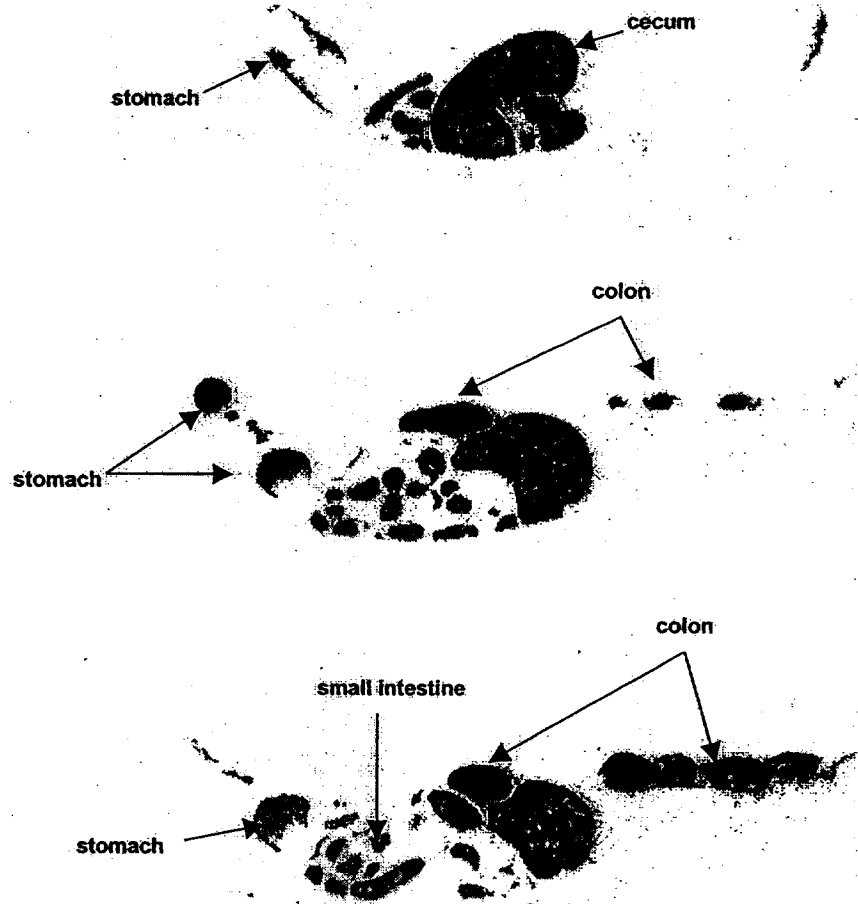


C8435

Male 12 hour

### Figure 3

Whole Body Autoradiograph of Female Fischer 344 Rat 24 Hours Following Administration of a Single Oral Dose of Polydimethylsiloxane, 350 cst.

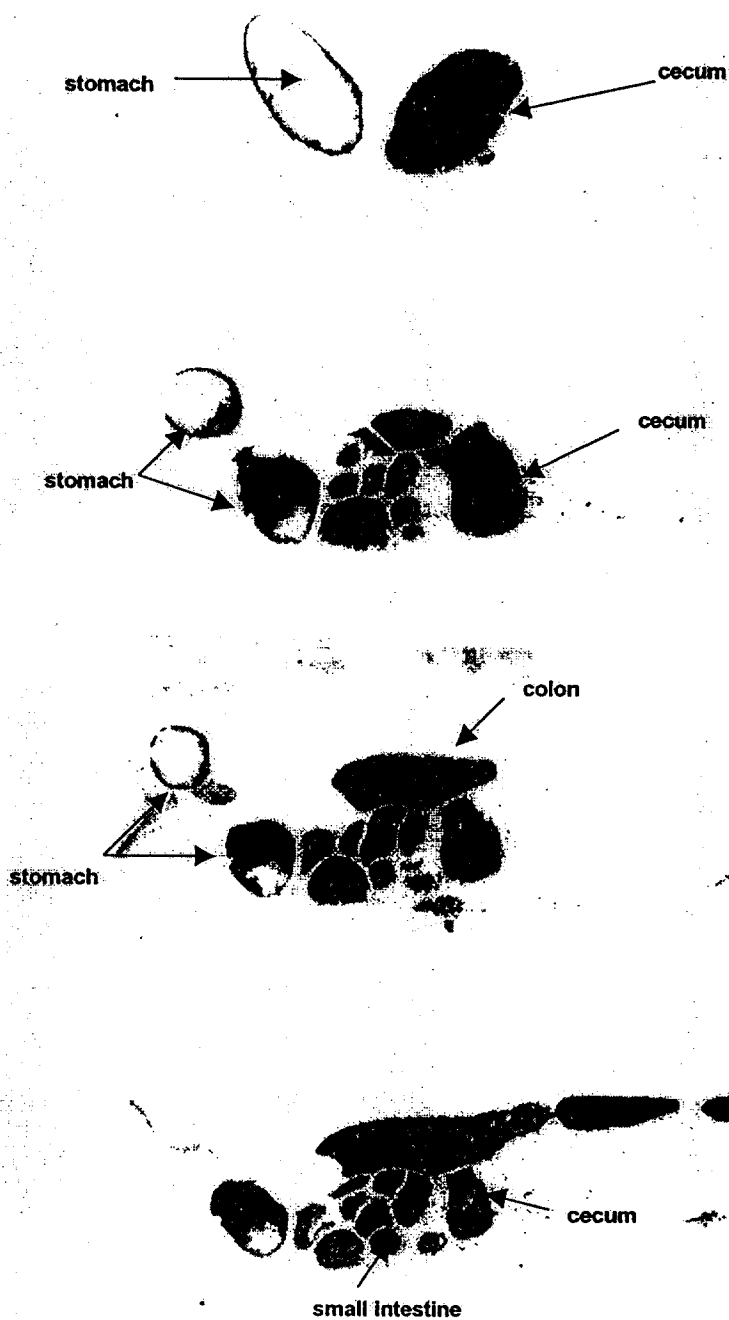


G8432

Female 24 hour

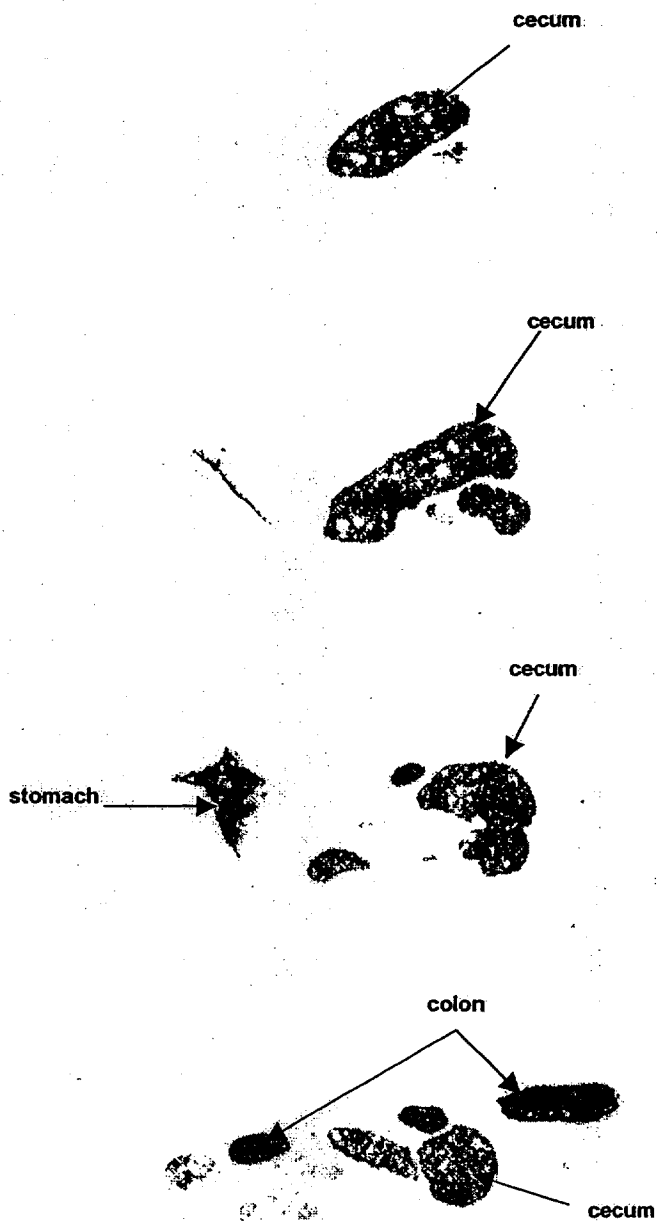
**Figure 4**

Whole Body Autoradiograph of Male Fischer 344 Rat 24 Hours Following Administration of a Single Oral Dose of Polydimethylsiloxane, 350 cst.

**C8436****Male 24 hour**

## Figure 5

Whole Body Autoradiograph of Female Fischer 344 Rat 48 Hours Following Administration of a Single Oral Dose of Polydimethylsiloxane, 350 cst.

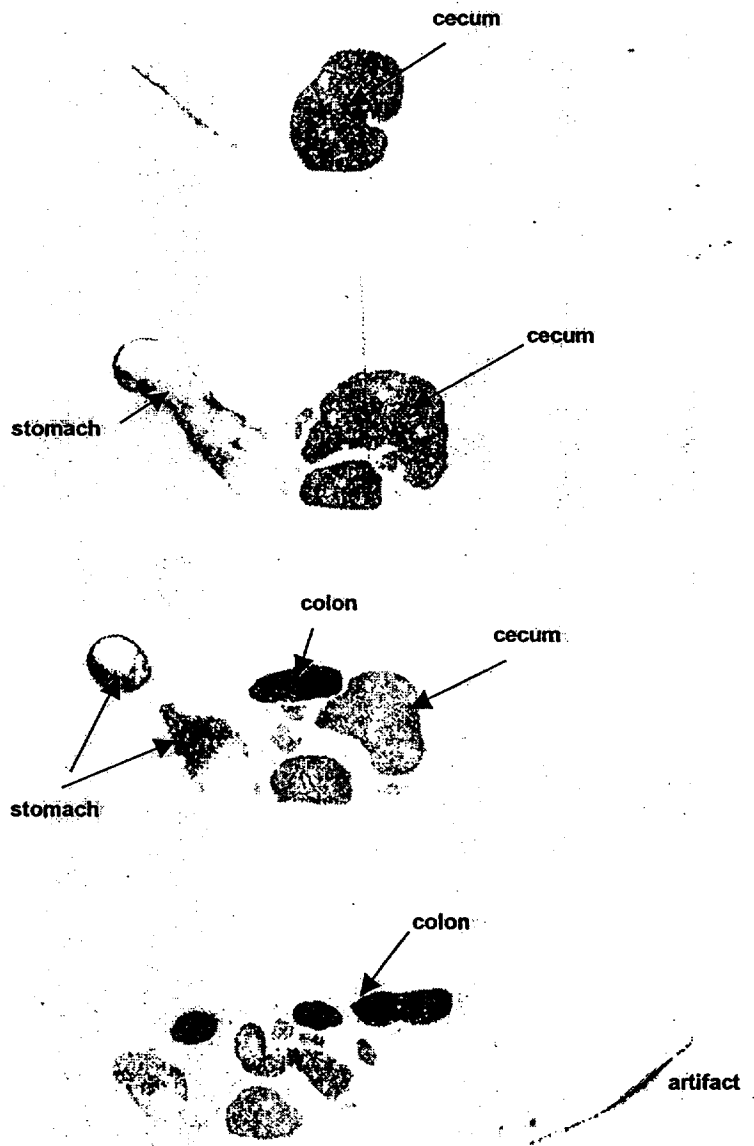


C8433

Female 48 hour

## Figure 6

Whole Body Autoradiograph of Male Fischer 344 Rat 48 Hours Following  
Administration of a Single Oral Dose of Polydimethylsiloxane, 350 cst.



C8437

Male 48 hour

## Figure 7

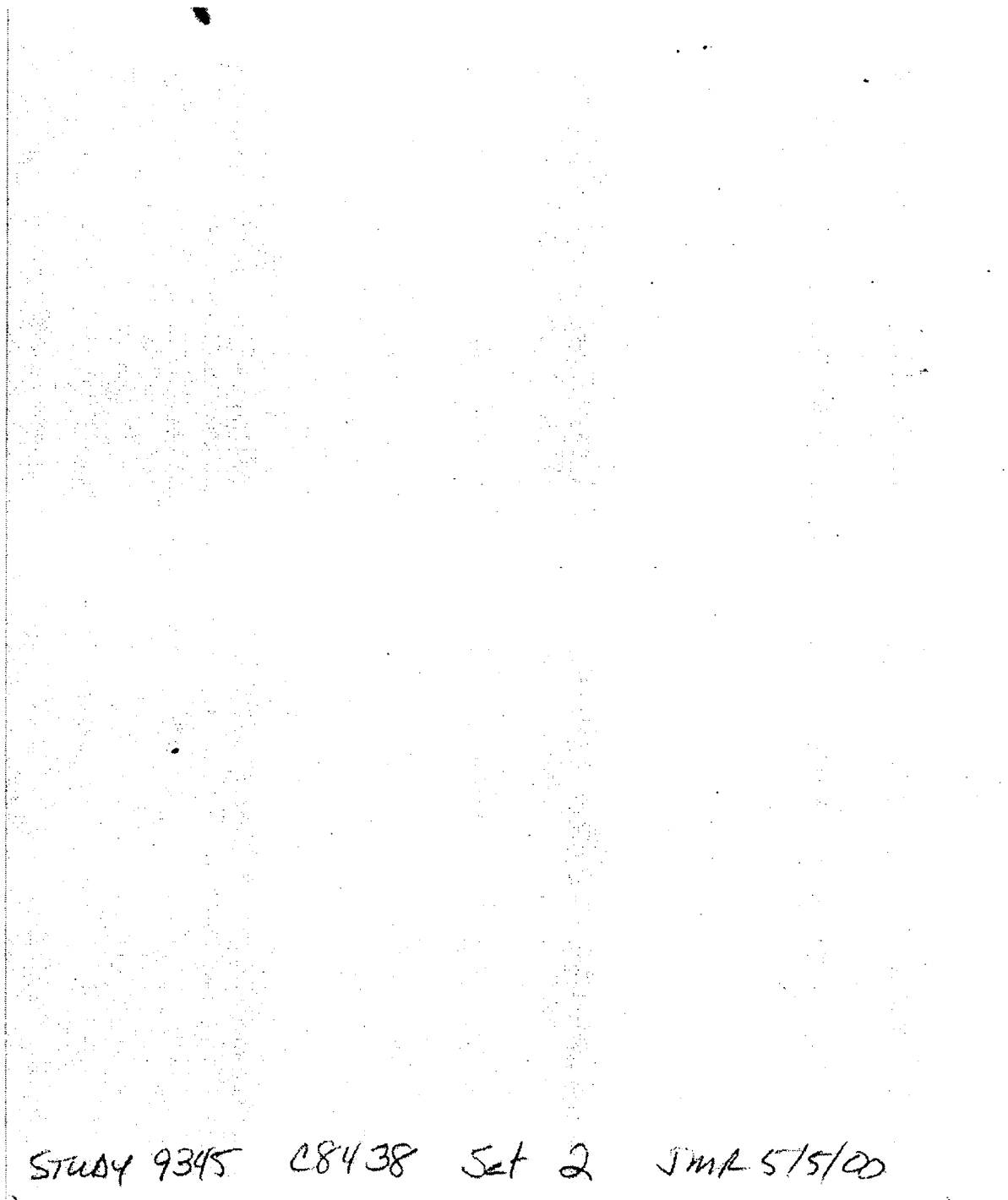
Whole Body Autoradiograph of Female Fischer 344 Rat 96 Hours Following  
Administration of a Single Oral Dose of Polydimethylsiloxane, 350 cst.

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C8434

## Figure 8

Whole Body Autoradiograph of Male Fischer 344 Rat 96 Hours Following  
Administration of a Single Oral Dose of Polydimethylsiloxane, 350 cst.



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C8438

Male 96 hour